Supreme Court, U.S.
FILED
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92-800

No. 92-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Petitioner,

v.

KATHLEEN E. LES; FRANCES LES THOMAS; MANUEL JESUS PEREZ MORALES; DAVID R. PEREZ; MANUEL R. PEREZ,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Does the United States Environmental Protection Agency have authority to establish a "*de minimis*" exception to § 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the food additive "Delaney clause") to allow use of agricultural pesticides which are carcinogenic in laboratory animals, but pose virtually no risk of cancer to consumers of processed foods?

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
TABLE OF AUTHORITIES	ii
OPINIONS BELOW	1
JURISDICTION	2
STATUTORY PROVISIONS INVOLVED	2
STATEMENT OF THE CASE	2
A. The Statutory Scheme for Pesticides	3
B. Proceedings Below	9
REASONS FOR GRANTING THE WRIT	11
I. THE NINTH CIRCUIT'S DECISION HAS FAR-REACHING CONSEQUENCES FOR THE PUBLIC, AGRICULTURE, THE FOOD AND PESTICIDE INDUSTRIES, AND EPA'S PESTICIDE REGULATORY PROGRAM	11
II. THE NINTH CIRCUIT'S DECISION CONFLICTS WITH THE *DE MINIMIS* DOCTRINE LONG RECOGNIZED BY THIS COURT	15
III. THE NINTH CIRCUIT'S DECISION CONFLICTS WITH THE D.C. CIRCUIT'S DELANEY CLAUSE *DE MINIMIS* ANALYSIS IN *PUBLIC CITIZEN v. YOUNG*	18
IV. THE NINTH CIRCUIT'S DECISION FAILS TO AFFORD DEFERENCE TO EPA'S INTERPRETATION OF THE STATUTORY SCHEME WHICH IT ADMINISTERS	22
CONCLUSION	26

TABLE OF AUTHORITIES

Cases	Page
Abbott Laboratories v. Portland Retail Druggists Ass'n, Inc., 425 U.S. 1 (1976)	16
Alabama Power Co. v. Costle, 636 F.2d 323 (D.C. Cir. 1980)	15,19,20,23
Boston Sand & Gravel Co. v. United States, 278 U.S. 41 (1928)	23
Chemical Manufacturers Ass'n v. Natural Resources Defense Council, Inc., 470 U.S. 116 (1985)	23
Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984)	24
Cook Inlet Native Ass'n v. Bowen, 810 F.2d 1471 (9th Cir. 1987)	23,24
Get Oil Out! Inc. v. Exxon Corp., 586 F.2d 726 (9th Cir. 1978)	25
Green v. Bock Laundry Machine Co., 490 U.S. 504 (1989)	23
Hudson v. McMillian, 112 S. Ct. 995 (1992)	16
Industrial Ass'n of San Francisco v. United States, 268 U.S. 64 (1925)	16
Industrial Union Department v. American Petroleum Institute, 448 U.S. 607 (1980)	15
Ingraham v. Wright, 430 U.S. 651 (1977)	16
Les v. Reilly, 968 F.2d 985 (9th Cir. 1992)	1
Love v. Thomas, 858 F.2d 1347 (9th Cir. 1988), *cert. denied*, 490 U.S. 1035 (1989)	24
Nader v. EPA, 859 F.2d 747 (9th Cir. 1988), *cert. denied*, 490 U.S. 1034 (1989)	3
People v. Reilly, No. CIV S-89-0752 WBS/GGH (E.D. Cal. filed May 24, 1989)	10
Public Citizen v. United States Department of Justice, 491 U.S. 440 (1989)	23

Table of Authorities Continued

	Page
Public Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988)	18,19,20,21,23
Republic of Argentina v. Weltover, Inc., 112 S. Ct. 2160 (1992)	16
Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984)	3
Wisconsin Department of Revenue v. William Wrigley, Jr., Co., 112 S. Ct. 2447 (1992)	16,17
Wisconsin Public Intervenor v. Mortier, 111 S. Ct. 2476 (1991)	3
STATUTES	
Fed. R. Civ. P. 41(b)	11
Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C.A. §§ 301-394 (West 1972 & Supp. 1992)	2
21 U.S.C. § 321(s)	6
21 U.S.C. § 342(a)(2)(C)	6,7,19
21 U.S.C. § 346a	*passim*
21 U.S.C. § 346a(a)	5
21 U.S.C. § 346a(b)	5
21 U.S.C. § 348	*passim*
21 U.S.C. § 348(a)(2)	6
21 U.S.C. § 348(c)(3)(A)	i,3,7
21 U.S.C. § 348(g)(1)	9
21 U.S.C. § 348(h)	10
21 U.S.C. § 376(b)(5)(B)	18

Table of Authorities Continued

	Page
Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y (1988 & Supp. III 1991)	2
7 U.S.C. § 136(bb)	4,21
7 U.S.C. § 136a	3
7 U.S.C. § 136a(c)(3)(8)	4
7 U.S.C. § 136a(c)(5)	3,21
7 U.S.C. § 136a-1	4
7 U.S.C. § 136d(b)	4
7 U.S.C. § 136d(c)	4
28 U.S.C. § 1254(1) (1988)	2
REGULATIONS	
Reorg. Plan No. 3 of 1970, §§ 2(a)(4), 2 (a)(8)(i), 40 C.F.R. pt. 1 (1970), *reprinted in* 5 U.S.C. app. at 1343 (1988)	5,26
40 C.F.R. § 152.112(g) (1992)	7
40 C.F.R. pt. 158 (1992)	4
35 Fed. Reg. 15,623 (1970)	26
53 Fed. Reg. 41,104 (Oct. 19, 1988)	5,8,10,22
55 Fed. Reg. 17,560 (Apr. 25, 1990)	22
56 Fed. Reg. 7750 (Feb. 25, 1991)	*passim*
57 Fed. Reg. 20,481 (May 13, 1992)	6,8,10,22
OTHER AUTHORITIES	
104 Cong. Rec. 17,412 (1958), *reprinted in* XIV HEW, *A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments* (1979)	25
S. Rep. No. 334, 95th Cong., 1st Sess. (1977)	21
S. Rep. No. 346, 100th Cong., 2d Sess. (1988)	21

Table of Authorities Continued

Page

S. Rep. No. 838, 92d Cong., 2d Sess., *reprinted in* 1972 U.S.C.C.A.N. 3993 4,21

Before the Subcomm. on Environment, Energy, and Natural Resources of the House Comm. on Government Operations (July 23, 1992) (statement of Linda J. Fisher, Assistant Administrator for Prevention, Pesticides and Toxic Substances, EPA) 13,14

Maura Dolan, *Court Bans 4 Chemicals from Processed Foods*, L.A. Times, July 8, 1992 14

Luise Light, Institute for Science in Society, *Unraveling Delaney's Paradox: Challenges for the 102nd Congress* (1991) 8

William K. Reilly, Remarks at the National Agricultural Chemicals Association Annual Meeting (Sept. 28, 1992) 13

Keith Schneider, *Court Expands Pesticide Ban to Cover Many Used in Food*, N.Y. Times, July 9, 1992 14

Michael Weisskopf, *Court Curbs Carcinogenic Pesticide Use*, Wash. Post, July 9, 1992 14

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Ninth Circuit is reported as *Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992), and is reproduced in the Appendices to this Petition as Appendix ("App.") A at 1a. The Final Order of the United States Environmental Protection Agency ("EPA") reviewed by the court of appeals was published at 56 Fed. Reg.

7750 (Feb. 25, 1991), and is reproduced as App. B at 12a.[1]

JURISDICTION

The judgment of the court of appeals was entered on July 8, 1992. A petition for rehearing was filed by EPA and denied on September 25, 1992. This Court has jurisdiction under 28 U.S.C. § 1254(1) (1988).

STATUTORY PROVISIONS INVOLVED

The two federal statutes involved in this case are the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C.A. §§ 301-394 (West 1972 & Supp. 1992), and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y (1988 & Supp. III 1991). The pertinent portions of these statutes are reproduced in App. C at 115a (FFDCA) and 121a (FIFRA).

STATEMENT OF THE CASE

Technological advances now make it possible to calculate human health risks more insignificant than ever before identifiable. Does EPA have authority, despite the antiquated language of FFDCA's food additive

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[1] Petitioner National Agricultural Chemicals Association ("NACA"), which has no corporate parent or subsidiaries, is a national, nonprofit trade association whose members manufacture, formulate and distribute virtually all of the agricultural pesticides used in the United States. NACA intervened below in support of EPA and its Administrator, William K. Reilly, the respondents below. The AFL-CIO, Natural Resources Defense Council, and Public Citizen were petitioner-intervenors below.

"Delaney clause," 21 U.S.C. § 348(c)(3)(A) (1988), to take these scientific advances into account by allowing the use of agricultural pesticides which have been found to induce cancer in laboratory animals, but whose residues in processed foods pose no more than a trivial (i.e., practically nonexistent) dietary risk of cancer to consumers? The American public, agriculture, the food and pesticide industries, and EPA's pesticide regulatory program, are directly affected by this nationally significant issue.

A. The Statutory Scheme for Pesticides

The food additive Delaney clause is a small and anomalous part of the pesticide regulatory scheme. Pesticides are regulated primarily under FIFRA, which this Court has accurately described as "a comprehensive regulatory statute." *Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476, 2480 (1991) (quoting *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984)). Before a pesticide can be sold or distributed, it must be granted a registration by EPA pursuant to FIFRA. *See* 7 U.S.C. § 136a. "A pesticide may be registered only if it does not cause 'unreasonable adverse effects' on human health or the environment, a standard that is applied by weighing the benefits of a pesticide against its risks." *Nader v. EPA*, 859 F.2d 747, 748 (9th Cir. 1988), *cert. denied*, 490 U.S. 1034 (1989).[2] To implement this FIFRA risk-benefit standard, "EPA is required . . . to consider

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[2] FIFRA provides, *inter alia*, that "[t]he Administrator shall register a pesticide if the Administrator determines that . . . (C) it will perform its intended function without unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). "The term 'unreasonable adverse effects on the environment' means

the *degree of risk* posed by the pesticide and the benefits it provides" before determining whether it can be registered for use. App. B at 19a (emphasis added). Pesticide manufacturers must fulfill EPA's elaborate requirements for submission of numerous types of state-of-the-art scientific studies, including carcinogenicity feeding studies conducted on laboratory animals, so that EPA can make the risk-benefit determination mandated by FIFRA for each agricultural pesticide. *See* 40 C.F.R. pt. 158 (1992).[3]

EPA evaluates the safety and use of every agricultural pesticide under FIFRA's risk-benefit standard. Indeed, when Congress enacted the modern FIFRA in 1972, it recognized that "[w]hile appropriate pesticides properly used are essential to man . . . . [s]ome may be taken up in the food chain," and thus "[t]heir wise control *based on a careful balancing of benefit versus risk* to determine what is best for man is essential." S. Rep. No. 838, 92d Cong., 2d Sess. 4, *reprinted in* 1972 U.S.C.C.A.N. 3993, 3996 (emphasis added).

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any unreasonable risk to man or the environment, taking into account the economic, social, and environmental *costs and benefits* of the use of any pesticide." 7 U.S.C. § 136(bb) (emphasis added).

[3] FIFRA's risk-benefit standard also governs interim administrative review, cancellation, and suspension of previously registered pesticides. *See* 7 U.S.C. §§ 136a(c)(3)(8), 136d(b), 136d(c). In addition, the risk-benefit standard governs reregistration, a procedure which requires manufacturers to submit updated health and safety data so that EPA can determine whether a previously registered pesticide continues to meet the risk-benefit standard. *See* 7 U.S.C. § 136a-1.

FFDCA plays a subordinate role in the overall pesticide regulatory scheme. It fulfills an enforcement function by requiring EPA to establish tolerances (i.e., maximum allowable concentrations in crops and processed foods) for residues of agricultural pesticides whose safety is evaluated, and registration and use regulated, pursuant to FIFRA's risk-benefit standard.[4] Under FFDCA § 408 ("Tolerances for pesticide chemicals in or on raw agricultural commodities"), 21 U.S.C. § 346a, a food crop is deemed to be "adulterated," and hence subject to seizure, unless EPA has established a tolerance, or granted an exemption, for pesticide residues in or on the crop.[5] In setting a § 408 tolerance "to the extent necessary to protect the public health," EPA is required to "give appropriate consideration, among other relevant factors . . . to the necessity for the production of an adequate, wholesome, and economical food supply." 21 U.S.C. § 346a(b). Thus, § 408 "expressly gives [EPA] the authority to balance risks against benefits in determining appropriate tolerance levels" for pesticide residues in crops. 53 Fed. Reg. 41,104, 41,106 (Oct. 19, 1988). This FFDCA risk-benefit standard *also* applies to pesticide residues which unavoidably "flow through" from crops into processed foods, provided that they do not

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[4] Since 1970 EPA has been responsible for administering FFDCA as it relates to establishing tolerances for pesticide residues. *See* 21 U.S.C. § 346a; Reorg. Plan No. 3 of 1970, §§ 2(a)(4), 2(a)(8)(i), 40 C.F.R. pt. 1 (1970), *reprinted in* 5 U.S.C. app. at 1343, 1344 (1988) (transfer of functions). The Food and Drug Administration retains responsibility only for inspecting crops and processed food products to ensure that any pesticide residues present are within the tolerance limits established by EPA.

[5] The only exception is for pesticides "generally recognized . . . as safe for use." 21 U.S.C. § 346a(a).

exceed § 408 tolerance levels. FFDCA § 402(a)(2)(C), 21 U.S.C. § 342(a)(2)(C).

Unlike § 408, which was enacted in 1954 and is specifically directed to pesticides, § 409 ("Food additives"), 21 U.S.C. § 348, enacted in 1958, is not a pesticide-specific tolerance provision. Under § 409, a "food additive," broadly defined in 21 U.S.C. § 321(s), is deemed to be unsafe, and hence, food containing the additive is regarded as adulterated and subject to seizure, unless there is a food additive regulation (i.e., § 409 tolerance) "prescribing the conditions under which such additive may be safely used." 21 U.S.C. § 348(a)(2).[6] Because of the § 402(a)(2)(C) "flow-through" provision, § 409 tolerance requirements apply only to pesticides whose residues "concentrate" in processed foods beyond § 408 tolerance levels.[7]

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[6] A "food additive" is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C. § 321(s). EPA has interpreted this definition for purposes of § 409 tolerance requirements as encompassing certain pesticide residues in processed foods. *See* 57 Fed. Reg. 20,481, 20,482-83 (May 13, 1992). In contrast, the statutory definition expressly excludes "a pesticide chemical in or on a raw agricultural commodity; or . . . a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity." 21 U.S.C. § 321(s).

[7] In absolute terms the amount of pesticide residue in a processed food is no greater than in or on the crop from which the food was processed. "Concentration" of a pesticide residue (i.e., a relative increase in the volume of the residue in comparison to the volume of the food) results from processing of the food itself. Thus, the same pesticide residues which are within § 408 tolerance limits, and hence legal, on a raw food (e.g., apples)

The language of the food additive Delaney clause, the thirty-five-year-old proviso in § 409(c)(3)(A) at the heart of this case, is totally inconsistent with the risk-benefit standard underlying FIFRA and FFDCA §§ 408 and 402(a)(2)(C). It states "[t]hat no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." 21 U.S.C. § 348(c)(3)(A). Read literally, this zero-risk language bars EPA from establishing § 409 tolerances for pesticide residues which pose even a trivial risk of cancer to consumers. For example, EPA may determine, on the basis of state-of-the-art studies, that a pesticide shows some evidence of carcinogenicity in laboratory animals, but poses no more than a negligible human dietary risk of cancer. That pesticide would be eligible for registration under FIFRA's risk-benefit standard, and also would be eligible to receive tolerances for use on food crops under the risk-benefit standard of FFDCA § 408. Under a rigid construction of the Delaney clause, however, the same pesticide would be ineligible for § 409 tolerances.

EPA's policy is "to refuse FIFRA registration and section 408 tolerances for those food uses of a pesticide that require a section 409 food additive regulation but run afoul of a strict reading of the Delaney Clause." App. B at 100a; *see* 40 C.F.R. § 152.112(g) (1992). As a result, the Delaney clause can effectively

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would render a food processed from that raw food (e.g., applesauce) adulterated if the residues "concentrate" beyond § 408 limits and no § 409 tolerance has been set.

block the use of agricultural pesticides which are vital to food production and pose only a trivial risk of cancer to consumers, but which require § 409 tolerances. Paradoxically, agricultural pesticides whose residues in processed foods do not exceed § 408 tolerance limits, and hence do not require § 409 tolerances, may be used if they satisfy the risk-benefit standards of FIFRA and FFDCA § 408, even if they pose higher-than-negligible carcinogenic risks to consumers. *See* App. B at 19a-21a (discussing the "Delaney paradox").[8]

In October 1988 EPA announced a *de minimis* exception to the § 409 Delaney clause "where the human dietary risk from residues of the pesticide is at most negligible." 53 Fed. Reg. 41,104; *see also* App. B; 57 Fed. Reg. at 20,482.[9] EPA has explained that this *de minimis* exception is necessary to regulate negligible-risk pesticides in a rational and consistent manner under FIFRA and FFDCA.

> [T]he Delaney Clause does not simply introduce an incongruity into the regulation of pesticides, it *actively interferes with the pri-*

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[8] A higher-than-negligible risk is not necessarily a significant risk. *See* App. B at 32a-45a. If a pesticide's residues in a processed food product did pose a significant risk to consumers, that presumably would tip the risk-benefit balance toward denial or cancellation of the pesticide's FIFRA registration.

[9] EPA generally regards a probability of 1 additional cancer case for every 1 million persons every 70 years as an upperbound negligible risk. *See* App. B at 33a. A negligible or trivial risk is "virtually a zero risk—too small to be of public health significance." Luise Light, Institute for Science in Society, *Unraveling Delaney's Paradox: Challenges for the 102nd Congress* 10 (1991).

> *mary framework for pesticide regulation as established by FIFRA and FFDCA section 408.* . . . [T]he Delaney Clause *directly subverts the risk/benefit balancing* that Congress so often has stated is crucial to the regulation of pesticides.
>
> Interpreting the Delaney Clause as containing a *de minimis* exception helps to reduce the conflict in the FFDCA and between the FFDCA and FIFRA. At least as to pesticides which pose a trivial cancer risk, use of a *de minimis* exception will result in *consistent treatment* of these pesticides under FFDCA, section 408, and section 409. Thus, a *de minimis* exception *harmonizes* to a degree Congress' overall legislative design for the regulation of pesticides.

App. B at 101a (emphasis added). The *de minimis* exception enables EPA to take full advantage of modern risk assessment, rather than ignore it as does the Delaney clause. Indeed, the Delaney clause was enacted before it was possible to distinguish between significant and insignificant carcinogenic risks. *See* App. B at 101a-104a. Because the *de minimis* exception only applies to negligible risks, neither the *de minimis* exception, nor this case, involve pesticides which pose a significant risk of cancer to consumers.

B. Proceedings Below

The court of appeals reviewed (App. A), pursuant to 21 U.S.C. § 348(g)(1), a Final Order issued by EPA on February 25, 1991 (App. B). The Final Order, on the basis of the *de minimis* exception, refused to revoke certain § 409 tolerances which had been

granted for four specific pesticides (trifluralin, benomyl, phosmet, and mancozeb) that were identified in EPA's October 1988 *Federal Register* notice as having "evidence of carcinogenicity" in laboratory animals. *See* 53 Fed. Reg. at 41,119. The administrative process which led to the Final Order was initiated on May 24, 1989 when an anti-pesticide coalition comprised of the then Attorney General of California,[10] Public Citizen, the AFL-CIO, the Natural Resources Defense Council, and the individuals who are the Respondents herein, filed a petition with EPA pursuant to 21 U.S.C. § 348(h) seeking revocation of those (and other) § 409 tolerances on the ground that the *de minimis* exception is unlawful. *See* 54 Fed. Reg. 27,700 (June 30, 1989).[11]

The court of appeals set aside EPA's Final Order on the ground that "the language of the Delaney clause, its history and purpose all reflect that Congress intended the EPA to prohibit all additives that are carcinogens, regardless of the degree of risk involved." App. A at 2a-3a. The court found that the

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[10] The Attorney General of California did not join the petitioners or petitioner-intervenors in the court of appeals proceeding. It should be noted that on the same day the EPA administrative petition was filed, the same petitioners and petitioner-intervenors (including the Attorney General of California) filed a district court action which also challenges EPA's implementation of the § 409 food additive Delaney clause, including the *de minimis* exception. *People v. Reilly*, No. CIV S-89-0752 WBS/GGH (E.D. Cal. filed May 24, 1989).

[11] A supplemental Final Order issued by EPA in May 1992 reconfirmed the earlier determination denying the petition to revoke certain § 409 tolerances for mancozeb. *See* 57 Fed. Reg. 20,481; App. B at 112a. The supplemental Final Order was not reviewed by the court of appeals.

Delaney clause's "language is clear and mandatory. . . . The statute provides that once the finding of carcinogenicity is made, the EPA has no discretion." *Id.* at 6a-7a. In reaching this conclusion, the court rejected or ignored EPA's and NACA's arguments that the *de minimis* principle of statutory construction (*de minimis non curat lex*: "the law cares not for trifles") governs this case; that the Delaney clause should not be interpreted in isolation; that the language of the Delaney clause conflicts with Congress' overall legislative design for pesticides, which is dominated by FIFRA and its risk-benefit standard; that the Delaney clause should not be construed as extraordinarily rigid with respect to pesticides which pose only a trivial risk of cancer to consumers of processed food; and that great deference should be afforded to EPA's *de minimis* interpretation of the Delaney clause, since for more than two decades EPA has been the sole federal agency responsible for evaluating the safety of pesticides and implementing the substantive requirements of the pesticide regulatory scheme.

Following denial of EPA's petition for rehearing, the court on October 8, 1992 granted separate motions filed by Petitioner and EPA pursuant to Fed. R. Civ. P. 41(b) for a stay of the mandate pending application to this Court for a writ of certiorari.

REASONS FOR GRANTING THE WRIT

I. THE NINTH CIRCUIT'S DECISION HAS FAR-REACHING CONSEQUENCES FOR THE PUBLIC, AGRICULTURE, THE FOOD AND PESTICIDE INDUSTRIES, AND EPA'S PESTICIDE REGULATORY PROGRAM

If the Ninth Circuit's decision is allowed to stand, it will derail Congress' carefully balanced statutory

machinery for regulating the use of agricultural pesticides. EPA has indicated that dozens of widely-used agricultural pesticides may have to be banned. That would significantly disrupt production of commodities such as wheat, corn, soybeans, and cotton, and scores of fruit and vegetable crops. In turn, that would curtail the nation's supply of processed foods. Government agencies even may seize food products from processing plants and supermarket shelves on the theory that they are adulterated by unlawful pesticide residues. The public undoubtedly would lose confidence in the safety of the food supply, and pay higher prices for whatever processed food products remain available. Moreover, pesticide manufacturers would have no incentive for investing tens of millions of dollars in development of valuable, negligible-risk pesticides which would be barred from use as a result of the Ninth Circuit's Delaney clause decision.

EPA Administrator William K. Reilly, in remarks to the pesticide industry regarding the potential impact of the Ninth Circuit's decision, explained that

> [*t*]*he consequences of this court decision are potentially far-reaching and profound.*
>
> . . . . As a result of this decision, for example, low dietary risk pesticides could be removed from the market, *only to be replaced by pesticides posing potentially more harmful effects*. I'm no less concerned that this decision will divert EPA's energy and resources from more worthwhile actions—actions that are crucial to EPA, to farmers, and to NACA, like the registration of new and improved chemicals and re-registration of older ones.

William K. Reilly, Remarks at the National Agricultural Chemicals Association Annual Meeting 3 (Sept. 28, 1992) (emphasis added) (transcript available from EPA Office of Administrator).

Linda J. Fisher, EPA's Assistant Administrator for Prevention, Pesticides and Toxic Substances, testified before Congress that

> if the Ninth Circuit's decision stands at the end of the day, *I foresee far-reaching and dramatic impacts on pesticide use in this country*. While I wish that I could say that these changes will contribute measurably to the safety of the food supply, it is not at all clear that that would be true.

Before the Subcomm. on Environment, Energy, and Natural Resources of the House Comm. on Government Operations 22 (July 23, 1992) (statement of Linda J. Fisher, Assistant Administrator for Prevention, Pesticides and Toxic Substances, EPA) (emphasis added). She testified that "[t]he Ninth Circuit decision applies only to the four pesticides at issue in the litigation, but *the court's ruling logically would extend to numerous other pesticides* that have or need section 409 food additive tolerances." *Id.* at 19 (emphasis added). Ms. Fisher indicated that "[a]t this point EPA has identified roughly thirty (30) pesticides" which may have "violative residues" under the court's ruling. *Id.* "These pesticides, however, are *only a portion of the total universe that could be affected*, since there are *at least three dozen more pesticides* with registered food uses, and *some* evidence of carcinogenic effects." *Id.* (emphasis added). Moreover, Ms. Fisher testified that "EPA, in consultation with the Food and Drug

Administration, must carefully consider whether following the revocation of tolerances the government should take *enforcement actions against food in supermarkets and processing plants that contain residues that were previously legal.*" *Id.* at 21 (emphasis added).

Respondents have been no less emphatic regarding the substantial impact of the Ninth Circuit's ruling. Their lead counsel was quoted in many front page newspaper stories around the country after the court of appeals issued its decision. He proclaimed that "the ruling [is] 'the *Brown versus Board of Education* of the pesticide world,' establishing legal principles of pesticide regulation much as the landmark civil rights ruling did for desegregation." Michael Weisskopf, *Court Curbs Carcinogenic Pesticide Use*, Wash. Post, July 9, 1992, at A1. He also declared that "[t]his decision will provide a powerful catalyst to force American agriculture to get off the pesticide treadmill." Keith Schneider, *Court Expands Pesticide Ban to Cover Many Used in Food*, N.Y. Times, July 9, 1992, at A1, A16. He (like EPA) indicated that "[d]ozens" of agricultural pesticides "could be banned under the ruling." Maura Dolan, *Court Bans 4 Chemicals from Processed Foods*, L.A. Times, July 8, 1992, at A1.

In light of these sweeping ramifications, and the Ninth Circuit's erroneous reading of the Delaney clause, Supreme Court review of the *de minimis* issue is essential. A final determination by this Court not only is critically important to consumers, agriculture, and industry, but also to EPA, which is responsible for regulating public health risks in a rational, consistent, and scientifically sound manner.

II. THE NINTH CIRCUIT'S DECISION CONFLICTS WITH THE *DE MINIMIS* DOCTRINE LONG RECOGNIZED BY THIS COURT

" '[S]afe' is not the equivalent of 'risk-free.' " *Industrial Union Department v. American Petroleum Institute*, 448 U.S. 607, 642 (1980) (setting aside workplace benzene standard which OSHA promulgated after it concluded that there is no absolutely safe level for human exposure to carcinogens). "There are many activities that we engage in every day . . . that entail some risk of accident or material health impairment; nevertheless, few people would consider these activities 'unsafe.' " *Id.* In other words, "[s]ome risks are plainly acceptable." *Id.* at 655. For this reason, federal regulatory statutes confer upon agencies "[i]nherent . . . authority to refrain from regulation of insignificant or *de minimis* risks." *Id.* at 663-64 (Burger, J., concurring) (citing *Alabama Power Co. v. Costle*, 636 F.2d 323, 360-61 (D.C. Cir. 1980)).

The Ninth Circuit held that EPA lacks authority to exempt *de minimis* pesticide risks because the Delaney clause says what it says:

> The language is clear and mandatory. The Delaney clause provides that no additive shall be deemed safe if it induces cancer. . . . The statute provides that once the finding of carcinogenicity is made, the EPA has no discretion.

App. A at 6a-7a. This conclusion, reflecting the Ninth Circuit's rigid adherence to the literal language of the Delaney clause, squarely conflicts with the *de minimis* principle of statutory construction repeatedly recognized by this Court.

For example, last Term in *Wisconsin Department of Revenue v. William Wrigley, Jr., Co.*, 112 S. Ct. 2447 (1992), the Court considered the issue of whether there is a *de minimis* exception to an immunity provision in a state franchise tax statute. The immunity provision exempts from taxation out-of-state companies whose only in-state business activity is solicitation of sales orders. The question was whether the immunity provision encompassed certain additional, "*de minimis*" in-state business activities. The state tax agency asserted "that the plain language of the statute bars this recognition of a *de minimis* exception." *Id.* at 2457. The Court rejected the state's "plain language" argument because it

> ignores the fact that the venerable maxim *de minimis non curat lex* ("the law cares not for trifles") is part of the established background of legal principles *against which all enactments are adopted*, and which all enactments (absent contrary indication) are deemed to accept. See, *e.g.*, *Republic of Argentina v. Weltover, Inc.*, ___ U.S. ___, ___, 112 S.Ct. 2160, 2168, ___ L.Ed.2d ___ (1992); *Hudson v. McMillian*, 503 U.S. ___, ___, 112 S.Ct. 995, 1000, 117 L.Ed.2d 156 (1992); *Ingraham v. Wright*, 430 U.S. 651, 674, 97 S.Ct. 1401, 1414, 51 L.Ed.2d 711 (1977); *Abbott Laboratories v. Portland Retail Druggists Assn., Inc.*, 425 U.S. 1, 18, 96 S.Ct. 1305, 1316, 47 L.Ed.2d 537 (1976); *Industrial Assn. of San Francisco v. United States*, 268 U.S. 64, 84, 45 S.Ct. 403, 408, 69 L.Ed. 849 (1925).

Id. at 2457-58. The Ninth Circuit's "plain language" interpretation of the Delaney clause ignores this *de minimis* principle.

Noting that an out-of-state company would be liable for hundreds of thousands of dollars in taxes if a salesman sold a 10-cent item in-state, the Supreme Court emphasized in *Wrigley* that "[i]t would be especially unreasonable to abandon normal application of the *de minimis* principle in construing [a statute] which operates in such *stark, all-or-nothing* fashion." *Id.* at 2458 (emphasis added). It would be just as unreasonable to abandon the *de minimis* principle in the case of the food additive Delaney clause, yet that is *exactly* what the Ninth Circuit did by holding that the clause "prohibit[s] all additives that are carcinogens, regardless of the degree of risk involved." App. A at 3a. Unless this Court reviews and reverses the Ninth Circuit's holding, the Delaney clause will operate in a stark, all-or-nothing (and completely irrational) fashion: It will effectively bar use of pesticides whose residues in processed foods exceed § 408 tolerance levels but pose only a trivial risk of cancer, while allowing use of pesticides whose residues in processed foods pose higher-than-negligible risks to consumers but do not require § 409 tolerances.

The Court explained in *Wrigley* that the mere presence of restrictive language in a statutory provision does not preclude a *de minimis* exception. The Court held that the tax immunity provision at issue in *Wrigley* "places a strict limit upon the *categories* of activities that are covered . . . not upon their *substantiality*." 112 S. Ct. at 2458. Similarly, the mere presence of restrictive language in the Delaney clause (i.e., language declaring that food additives which

"induce cancer" are unsafe) does not preclude a *de minimis* exception for pesticide residues which pose essentially a zero risk of inducing cancer in consumers. The Ninth Circuit missed this critical point completely, holding instead that the Delaney clause's "language is clear and mandatory," even for trivial risks. App. A at 6a.

III. THE NINTH CIRCUIT'S DECISION CONFLICTS WITH THE D.C. CIRCUIT'S DELANEY CLAUSE *DE MINIMIS* ANALYSIS IN *PUBLIC CITIZEN v. YOUNG*

The court of appeals unjustifiably cited *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988), as authority for rejection of EPA's *de minimis* interpretation of the food additive Delaney clause. *See* App. A at 7a. In *Public Citizen* the D.C. Circuit concluded "with some reluctance" that a *de minimis* exception cannot be read into FFDCA's *color* additive Delaney clause, 21 U.S.C. § 376(b)(5)(B) (1988), a wholly separate provision. 831 F.2d at 1109. The D.C. Circuit emphasized that "the operation of the food additive Delaney Clause raises complex issues distinct from those" raised in the color additive Delaney clause; that "[a]lthough the clauses have almost identical wording, the context is clearly different"; and that the question of whether the food additive Delaney clause contains a *de minimis* exception is not "foreordained" by the court's decision on the color additive Delaney clause. *Id.* at 1118 n.13, 1120.

The Ninth Circuit disregarded not only these caveats, but also the *de minimis* principles which the D.C. Circuit articulated and followed in the *Public Citizen* case. In particular, the Ninth Circuit utterly failed to consider whether EPA's *de minimis* excep-

tion serves as a "tool to be used in implementing the legislative design" for pesticides. *Id.* at 1113 (quoting *Alabama Power Co. v. Costle*, 636 F.2d at 360). The D.C. Circuit explained that the *de minimis* doctrine "must be interpreted with a view to 'implementing the legislative design'" because failure to employ a *de minimis* exception "may lead to regulation that not only is 'absurd or futile' in some general cost-benefit sense but also is directly contrary to the *primary* legislative goal." *Id.*

Despite the fact that FIFRA is the *principal* pesticide regulatory statute, and although its risk-benefit standard *dominates* Congress' legislative design for pesticides, *the Ninth Circuit virtually ignored FIFRA*, mentioning it only in passing. *See* App. A at 10a. This gaping omission renders the court's scant *de minimis* "analysis" wholly inadequate and patently defective.

The court failed to consider the manner in which the *de minimis* exception helps to implement Congress' legislative design for pesticides by enabling EPA to avoid, for negligible-risk pesticides, the obvious conflict between the Delaney clause and FIFRA's risk-benefit standard. *See* App. B at 98a-100a. Instead, the court purported to deal with "the overall statutory scheme governing pesticides" by briefly discussing the relationship between FFDCA §§ 409 and 402(a)(2)(C), and then focusing almost exclusively on the Delaney clause itself. App. A at 7a-8a. Having failed even to recognize the conflict between the Delaney clause and the risk-benefit standard contained in FFDCA § 408, the court erroneously concluded that § 402(a)(2)(C) (the "flow-through" provision which incorporates the § 408 risk-benefit standard) "expressly

harmonizes [the pesticide] scheme with the Delaney clause." *Id.* To the contrary, it is the *de minimis* exception which harmonizes, for pesticides which pose trivial risks, the Delaney clause with Congress' legislative design for pesticides.

In *Public Citizen* the D.C. Circuit described

> the standard for application of *de minimis* as virtually a *presumption in its favor*: "Unless Congress has been extraordinarily rigid, there is likely a basis for an implication of *de minimis* authority to provide [an] exemption where the burdens of regulation yield a gain of trivial or no value."

831 F.2d at 1113 (quoting *Alabama Power*, 636 F.2d at 360-61) (emphasis added). Because the Ninth Circuit ignored this presumption and read the Delaney clause and its legislative history in isolation, rather than in the context of the full pesticide regulatory scheme, the court erroneously concluded that Congress intended the clause to be applied with "rigidity," including with respect to pesticide residues in processed foods. App. A at 8a-9a. Yet the court acknowledged that the legislative history of § 409 "does not focus on pesticides." *Id.* at 10a.

The court did not consider the vast majority of Congress' statutory scheme for pesticides, including especially FIFRA and its legislative history, and as a result, failed to recognize that Congress could not have intended the Delaney clause to be "extraordinarily rigid" with respect to negligible-risk pesticides. Such an interpretation of the Delaney clause directly conflicts with the risk-benefit standard which overwhelmingly pervades the pesticide regulatory scheme,

and *authorizes* use of beneficial pesticides which pose merely a trivial risk of cancer.

In *Public Citizen* the D.C. Circuit found that Congress intended the legislative design for *color* additives to be "extraordinarily rigid," thereby precluding a *de minimis* interpretation of the color additive Delaney clause, because Congress "perceived color additives as lacking any great value. . . . there is evidence that Congress thought the public could get along without carcinogenic colors." 831 F.2d at 1117. Exactly the *opposite* is true for agricultural pesticides, the necessity for which Congress has repeatedly stressed. When Congress modernized FIFRA in 1972, it incorporated consideration of the "economic, social, and environmental . . . benefits" of pesticides into the statutory risk-benefit standard for registration, explaining that "[p]esticides are essential to man's food supply both as to quality and quantity." 7 U.S.C. §§ 136a(c)(5), 136(bb); S. Rep. No. 838, 92d Cong., 2d Sess. 3, *reprinted in* 1972 U.S.C.C.A.N. 3993, 3995. In 1977 Congress reaffirmed that "[a]n overriding concern of FIFRA is that pesticides should be available to meet pest control needs." S. Rep. No. 334, 95th Cong., 1st Sess. 3, 5 (1977). Similarly, when Congress accelerated FIFRA's reregistration procedures in 1988, it sought to ensure "that pesticides are approved and used in a manner that meets contemporary health and safety standards [and] that affordable and effective products are available to pesticide users." S. Rep. No. 346, 100th Cong., 2d Sess. 6 (1988).

By misplacing reliance on *Public Citizen*'s color additive findings and disregarding the *de minimis* principles which govern this case, the Ninth Circuit has

held unlawful EPA's *de minimis* interpretation without even considering the critically important role that the *de minimis* exception fulfills in avoiding the conflict between the zero-risk language of the food additive Delaney clause and the risk-benefit standard mandated by FIFRA and by FFDCA's pesticide-specific tolerance provisions. EPA has explained that "[t]he *de minimis* exception simply recognizes that the Delaney Clause should not be a bar to the use of a pesticide that satisfies the statutory standard of FIFRA [and FFDCA § 408] for a carcinogenic pesticide which presents a trivial risk." 55 Fed. Reg. 17,560, 17,565-66 (Apr. 25, 1990). This is a point which the court of appeals ignored entirely.

IV. THE NINTH CIRCUIT'S DECISION FAILS TO AFFORD DEFERENCE TO EPA'S INTERPRETATION OF THE STATUTORY SCHEME WHICH IT ADMINISTERS

Since its creation in 1970, EPA has been the *sole* agency responsible for administering the substantive provisions of the federal statutory scheme for pesticides, including the FFDCA § 409 Delaney clause as it pertains to pesticide residues in processed foods.[12] The Final Order which the court of appeals reviewed contains an exhaustive discussion of the basis for EPA's *de minimis* interpretation. *See* App. B at 17a-108a; *see also* 53 Fed. Reg. at 41,104-10; 55 Fed. Reg. at 17,560-74; 57 Fed. Reg. at 20,482-85. Nevertheless, the Ninth Circuit gave no deference to EPA, and erroneously characterized EPA's rationale for the

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[12] As noted, FDA merely inspects crops and processed foods to enforce the tolerance requirements which EPA establishes pursuant to FFDCA §§ 408 and 409.

de minimis exception as an attempt to "[r]evis[e] the existing statutory scheme." App. A at 11a.

The court missed the whole point of the *de minimis* doctrine: "The ability . . . to exempt *de minimis* situations from a statutory command is not an ability to depart from the statute, but rather a tool to be used in implementing the legislative design." *Alabama Power Co. v. Costle*, 636 F.2d at 360. Thus, "[c]ourts (and agencies) are not . . . helpless slaves to literalism." *Public Citizen v. Young*, 831 F.2d at 1112. "Where the literal reading of a statutory term would 'compel an odd result,' " it is appropriate to "search for other evidence of congressional intent." *Public Citizen v. United States Department of Justice*, 491 U.S. 440, 454 (1989) (quoting *Green v. Bock Laundry Machine Co.*, 490 U.S. 504, 509 (1989)). "Looking beyond the naked text for guidance is perfectly proper . . . where [the result] seems inconsistent with Congress' intention, since the plain-meaning rule is 'rather an axiom of experience than a rule of law, and does not preclude consideration of persuasive evidence if it exists.' " 491 U.S. at 455 (quoting *Boston Sand & Gravel Co. v. United States*, 278 U.S. 41, 48 (1928)).

As the agency responsible for implementing Congress' legislative design for pesticides, EPA has adopted a *de minimis* interpretation of the food additive Delaney clause to harmonize it with FIFRA and the pesticide-specific tolerance provisions of FFDCA. The language of a statute should not be construed "to mandate a result in one clause, only to preclude that result in the next clause." *Cook Inlet Native Ass'n v. Bowen*, 810 F.2d 1471, 1474 (9th Cir. 1987); *see also Chemical Manufacturers Ass'n v. Natural Re-*

sources Defense Council, Inc., 470 U.S. 116, 126 (1985). Instead, "[t]he words of a statute should be harmonized internally and with each other to the extent possible." *Cook Inlet Native Ass'n v. Bowen*, 810 F.2d at 1474.

The *de minimis* interpretation is well within EPA's authority, and the Ninth Circuit should have given deference to it. This Court has "long recognized that considerable weight should be accorded to an [agency's] construction of a statutory scheme it is entrusted to administer." *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984).

As the Ninth Circuit recognized in a previous case involving FIFRA, it

> is often the case where Congress drafts complex statutes [that] the various provisions do not fit with surgical precision. While the statute's meaning may be clear as to most of the situations it covers, cases may arise where two provisions in the same statute, or in different statutes, apparently conflict.

Love v. Thomas, 858 F.2d 1347, 1354 (9th Cir. 1988), *cert. denied*, 490 U.S. 1035 (1989). That is the situation here. While the meaning of the Delaney clause may be clear with respect to non-pesticide food additives regulated exclusively under FFDCA, its zero-risk language conflicts with EPA's mandate under FIFRA and FFDCA § 408 to regulate pesticides based on balancing benefits against the degree of risk that they pose. For this reason, it is appropriate for EPA to construe these statutes "so that they are consistent with each other" with respect to pesticides that pose a trivial risk of cancer, "as by this means congres-

sional intent can be given its fullest expression." *Get Oil Out! Inc. v. Exxon Corp.*, 586 F.2d 726, 729 (9th Cir. 1978).

Rather than affording deference to EPA's interpretation of the Delaney clause insofar as it pertains to pesticides whose safety Congress entrusted EPA alone to evaluate, the court of appeals gave "great weight" to a 1958 "contemporaneous" interpretation by the now-defunct Department of Health, Education, and Welfare ("HEW") (of which FDA was a part). App. A at 9a. HEW's supposed administrative interpretation, however, did not focus on pesticides, and was in the form of a letter from the Secretary of HEW to a congressional committee endorsing the proposed FFDCA food additive amendment. *See* 104 Cong. Rec. 17,412, 17,415 (1958), *reprinted in* XIV HEW, *A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments* 869 (1979).[13] Moreover, FDA not only has been out of the pesticide tolerance-setting business for more than twenty-two years, it *never* was responsible for administering FIFRA.[14] Therefore, unlike EPA, which

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[13] According to the court, HEW "interpreted the clause as removing all agency discretion regarding carcinogens." App. A at 9a. What the Secretary of HEW actually said, however, was that "[t]his Department is in complete accord with the intent . . . that no substance should be sanctioned for uses in food that might produce cancer *in man*." 104 Cong. Rec. at 17,415 (emphasis added). Thus, the Secretary did not offer the extraordinarily rigid interpretation of the Delaney clause which the court suggests. Furthermore, the Secretary admonished the Committee "to use language that would provide the intended safeguards without creating unintended and unnecessary complications." *Id.*

[14] Prior to EPA's creation in 1970, the United States De-

has had decades of experience in implementing the *entire* pesticide regulatory scheme, and has unique expertise on how FIFRA and the Delaney clause interact, FDA was in no position to know in 1958, before the food additive Delaney clause even was enacted, that it would conflict with FIFRA and Congress' legislative design for pesticides.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

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partment of Agriculture was responsible for administering FIFRA. *See* 35 Fed. Reg. 15,623 (1970) (transferring to EPA pesticide regulatory functions of USDA under FIFRA and FDA under FFDCA pursuant to Reorg. Plan No. 3 of 1970, 40 C.F.R. pt. 1 (1970), *reprinted in* 5 U.S.C. app. at 1343 (1988)).

Supreme Court, U.S.
FILED
JAN 8 1993
OFFICE OF THE CLERK

No. 92-800

In the Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, PETITIONER

v.

KATHLEEN E. LES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether a pesticide residue regulated as a food additive that poses only a de minimis risk of cancer is "unsafe" within the meaning of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 348(c)(3)(A).

TABLE OF CONTENTS

	Page
Opinion below	1
Jurisdiction	1
Statement	2
Argument	5
Conclusion	9

TABLE OF AUTHORITIES

Cases:

Chevron U.S.A. Inc. v. *NRDC, Inc.*, 467 U.S. 837 (1984)	7, 8
Love v. *Thomas*, 858 F.2d 1347 (9th Cir. 1988), cert. denied, 490 U.S. 1035 (1989)	2, 5
Public Citizen v. *Young*, 831 F.2d 1108 (D.C. Cir. 1987), cert. denied, 485 U.S. 1006 (1988)	5, 6
Wisconsin Dep't of Revenue v. *William Wrigley, Jr., Co.*, 112 S. Ct. 2447 (1992)	7
Wisniewski v. *United States*, 353 U.S. 901 (1957)	5

Statutes and regulation:

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*:	
§ 402, 21 U.S.C. 342	2
§ 402(a)(2)(B), 21 U.S.C. 342(a)(2)(B)	3
§ 402(a)(2)(C), 21 U.S.C. 342(a)(2)(C)	3
§ 408, 21 U.S.C. 346a	2, 3, 4, 8
§ 408(b), 21 U.S.C. 346a(b)	3
§ 409, 21 U.S.C. 348	2, 3, 4, 8
§ 409(c)(3), 21 U.S.C. 348(c)(3)	3
§ 409(c)(3)(A), 21 U.S.C. 348(c)(3)(A)	2, 3, 4, 5, 6, 7, 8
§ 706, 21 U.S.C. 376	6
§ 706(b)(5)(B)(ii), 21 U.S.C. 376(b)(5)(B)(ii)	5
Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136-136y	2
7 U.S.C. 136(bb)	2
40 C.F.R. 177.1(c)	3

Miscellaneous: Page

56 Fed. Reg. 7750 (1991) 4

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OPINION BELOW

The opinion of the court of appeals, Pet. App. 1a-11a, is reported at 968 F.2d 985.

JURISDICTION

The judgment of the court of appeals was entered on July 8, 1992. A petition for rehearing was denied on September 25, 1992. The petition for a writ of certiorari was filed on November 6, 1992. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

This case involves efforts by the United States Environmental Protection Agency (EPA) to apply certain provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) in the context of pesticide residues on processed foods. In particular, under Section 402 of the FDCA, 21 U.S.C. 342, foods that contain unsafe food additives are deemed to be adulterated. A food additive is considered unsafe unless there is a specific regulation issued under Section 409 of the FDCA, 21 U.S.C. 348, describing the conditions under which the food additive may be considered safe. The so-called "Delaney Clause" in Section 409 (c) (3) (A) provides that "no [food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal." 21 U.S.C. 348(c) (3) (A).

1. The EPA regulates pesticides under two different statutes and three different legal standards. The most comprehensive of these statutes is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136-136y, which prescribes a licensing or registration system for pesticides sold or distributed in the United States. The standard for granting, cancelling, or suspending a pesticide registration is whether the pesticide poses "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(bb); see *Love* v. *Thomas*, 858 F.2d 1347, 1350 (9th Cir. 1988), cert. denied, 490 U.S. 1035 (1989).

The EPA also regulates pesticide residues in food under two separate provisions in the FDCA. Section 408 of the FDCA, 21 U.S.C. 346a, addresses pesticide residues in raw agricultural commodities. Under Sec-

tion 402(a)(2)(B) of the FDCA, 21 U.S.C. 342 (a)(2)(B), a raw agricultural commodity containing a pesticide residue is deemed adulterated unless that residue is authorized by a tolerance regulation or exemption from tolerance established under Section 408. To establish a tolerance regulation or exemption from a tolerance under Section 408, the EPA must find that the regulation will "protect the public health." 21 U.S.C. 346a(b). In reaching this determination, the EPA is required to consider the "necessity for the production of an adequate, wholesome, and economical food supply." 21 U.S.C. 346a(b). The EPA also regulates certain pesticide residues in some processed foods under Section 409 of the FDCA, 21 U.S.C. 348. Like Section 408, Section 409 establishes a scheme whereby processed foods containing a food additive are deemed adulterated unless the food additive has been authorized by a regulation. The EPA has interpreted the term "food additive" as applying to those pesticide residues in processed foods which exceed the tolerance for the relevant raw agricultural commodity. 40 C.F.R. 177.1(c). The establishment of a food additive regulation under Section 409 requires a finding under the "general safety clause" in Section 409(c)(3) that the use of a pesticide "will be safe." The general safety clause, in turn, is modified by the Delaney Clause.[1]

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[1] Only certain pesticide residues are regulated under Section 409 (and subject to the Delaney Clause) because of the "flow-through" provision in Section 402(a)(2)(C) of the FDCA, 21 U.S.C. 342(a)(2)(C). That provision establishes that Section 408 raw food tolerances "flow through" to cover pesticide residues in processed foods resulting from application of the pesticide to the raw food. Thus, if the concentration of the pesticide residue in the processed food does not exceed the

2. On February 25, 1991, the EPA issued a final order denying in part an administrative petition that had sought the revocation of several regulations issued under Section 409(c)(3)(A) of the FDCA, 21 U.S.C. 348(c)(3)(A). 56 Fed. Reg. 7750 (1991). The regulations covered certain pesticide residues in processed foods where the residues were found to be carcinogenic after the regulations had been originally established. The EPA denied the petition based on its conclusion that the Delaney Clause allowed the agency to adopt a de minimis exception for pesticide uses that posed a trivial risk of causing cancer. The EPA found that several of the pesticides posed only trivial risks of causing cancer and therefore declined to revoke the regulations permitting such residues on processed foods.[2]

3. Respondent Kathleen E. Les, among others,[3] sought review in the court of appeals of the EPA's final order, and the court of appeals reversed the EPA's decision. Pet. App. 1a-11a. According to that court, "the language of the Delaney clause, its history and purpose all reflect that Congress intended the EPA to prohibit all additives that are carcino-

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tolerance set for the raw agricultural commodity under Section 408, the residues may legally be present in the processed food without the need for setting and satisfying a separate tolerance under Section 409.

[2] The food additive regulations at issue set tolerances for 14 uses for seven separate pesticides. The lifetime risk of contracting cancer posed by the uses challenged by the respondents in the court of appeals was, at most, between approximately 1×10^{-7} and 2×10^{-11} (or approximately one in 10,000,000 and two in 100,000,000,000).

[3] We will hereafter use the term "respondents" to refer only to the non-federal respondents.

gens, regardless of the degree of risk involved." *Id.* at 2a-3a. The EPA therefore could not adopt a de minimis interpretation of that Clause. The court also ruled that the Delaney Clause unambiguously applies to the pesticide residues at issue in this case. *Id.* at 8a, 10a.

ARGUMENT

Although we disagree with the court of appeals' decision, we do not believe that the case warrants review by this Court.

1. There is no conflict among the circuits on the question presented in the petition; in fact, no other court of appeals has addressed that precise issue.[4] Moreover, the decision below is consistent with the D.C. Circuit's decision in *Public Citizen* v. *Young*, 831 F.2d 1108 (1987), cert. denied, 485 U.S. 1006 (1988), which held that a color additive that poses only a de minimis risk of cancer is "unsafe" within the meaning of the Color Additive Amendments of 1960 to the FDCA, 21 U.S.C. 376(b)(5)(B)(ii).[5]

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[4] The decision below also does not conflict with the Ninth Circuit's earlier decision in *Love* v. *Thomas*, 858 F.2d 1347 (1988), cert. denied, 490 U.S. 1035 (1989). That case involved review of an EPA decision under FIFRA, which requires the EPA to consider cost factors in registering or cancelling pesticide uses. The court held that the EPA's consideration of those factors in that particular case was inadequate. 858 F.2d at 1357-1363. *Love* addressed only the FIFRA question and did not involve the FDCA or the Delaney Clause. Nor did that case hold that the FIFRA cost-benefit standard overrides the zero-risk standard in the Delaney Clause. In any event, an alleged intracircuit conflict is for the court of appeals, not this Court, to resolve. *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957).

[5] The court in *Public Citizen* reserved comment on the question in this case, since that question did not arise there. 831 F.2d at 1118 n.13, 1120.

Petitioners argue that the decision below is inconsistent with *Public Citizen*, because, they maintain, the court of appeals failed to justify its holding in light of the apparently conflicting provisions of FIFRA and the FDCA. Pet. 18-22. That claim lacks merit.

In *Public Citizen*, a unanimous panel of the D.C. Circuit rejected the Food and Drug Administration's view that the Delaney Clause in Section 706 of the FDCA allowed the agency to adopt a de minimis exception to the otherwise flat ban in that provision. In so ruling, the D.C. Circuit pointed to three factors in determining whether a de minimis interpretation was appropriate: (1) whether the risk is negligible or trivial; (2) whether Congress had been extraordinarily rigid in its legislation, thereby evincing an intent to foreclose a de minimis exception; and (3) whether de minimis authority would further the legislative design or frustrate congressional intent. 831 F.2d at 1112-1113. The court concluded that the text and legislative history of the Color Additives Amendment precluded the FDA from adopting a de minimis exception to the Delaney Clause, because Congress had been extraordinarily rigid concerning the need for an anti-cancer clause, had carefully considered the need for the Delaney Clause, had exhaustively reviewed alternatives, and only then had emphatically rejected the alternatives. *Id.* at 1113-1115. Also, the court found that application of a strict standard was consistent with the safety goals of the legislation, given the relatively low societal value Congress placed on color additives. *Id.* at 1117-1118. Here, the court of appeals considered the EPA's argument that a de minimis exception helped resolve apparently conflicting congressional directives. Pet.

App. 7a, 10a. The court below therefore conducted the type of analysis that the D.C. Circuit set forth in *Public Citizen*.

Petitioner also argues that the court of appeals' decision "conflicts with the *de minimis* principle," Pet. 15, as recently articulated in *Wisconsin Dep't of Revenue* v. *William Wrigley, Jr., Co.*, 112 S. Ct. 2447 (1992). In that case, this Court stated that the principle of *de minimis non curat lex* is a "venerable maxim" of statutory construction and can be applied in matters of statutory interpretation "absent contrary indication." *Id.* at 2457-2458. In this case, the court of appeals found that the text, legislative history, and purposes of the Delaney Clause supply precisely the "contrary indication" necessary to preclude application of the de minimis principle. The decision below therefore does not conflict with the de minimis principle discussed in the *Wrigley* case.

2. Petitioner contends that the court of appeals failed to afford EPA appropriate deference in reviewing the agency's interpretation of the Delaney Clause. Pet. 22-26. That claim does not warrant further review.

It is well-settled that when a court reviews an administrative construction of a statute that an agency is responsible for administering, the court must determine whether Congress has resolved the particular question at issue. If Congress has done so, its resolution is binding on the agency and the courts. *Chevron U.S.A. Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 842-843 (1984). By contrast, if a reviewing court cannot find a clearly discernible congressional intent, "the court does not simply impose its own construction on the statute." *Id.* at 843. Instead, the court must determine whether the agency's construction is per-

missible or is "arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 844.

In this case, the court of appeals followed the analysis set forth in *Chevron*. It determined that Congress's intent regarding the meaning and effect of the Delaney Clause was clear and unambiguous. Pet. App. 3a-4a. The court cited evidence in the statutory text and legislative history as indicating that Congress intended the Delaney Clause to operate in a rigid fashion and that this rigid standard applied to the concentrating pesticides at issue in this case. Having reached that conclusion, it would not have been appropriate under *Chevron* for the court of appeals to have given deference to the agency's interpretation.

3. The adverse effects identified by petitioners may stem in part from EPA's policies and regulations regarding the coordination of its authority under Section 409 with its authority under Section 408 and FIFRA, rather than being the inevitable consequence of the Ninth Circuit's interpretation of the Delaney Clause.[6] Once this litigation is final, EPA will review its regulations and policies regarding the interrelation of its authorities concerning pesticides. EPA will determine whether changes in its policies and

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[6] For example, EPA has traditionally refused to register a pesticide use under FIFRA or approve a Section 408 raw food tolerance if EPA determines that there is a possibility that residues in a processed food could exceed the raw food tolerance and a Section 409 food additive regulation could not be approved. In the wake of the Ninth Circuit's decision in this case, various food processor and food growing groups have petitioned EPA to rescind that policy claiming it is both illegal and unsound. EPA is currently considering that petition.

regulations are legally permitted or possibly required, and, if EPA's authority is found to be permissive, whether any change is a rational policy choice. A change in EPA's policy may ameliorate many of the adverse consequences feared by petitioners. To be sure, changes in EPA's policy on coordinating its authorities over pesticides would represent a major alteration of the existing pesticide regulatory scheme as administered by EPA for the last 20 years. Such changes could have substantial impacts on consumers, growers, the pesticide industry, and EPA, and EPA will need to assess the extent of these effects in considering any policy changes. Nevertheless, due to the uncertainty regarding the type of effects that will result from the Ninth Circuit's decision, there is no need to grant discretionary review at this time.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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JANUARY 1993

☆ U. S. GOVERNMENT PRINTING OFFICE: 1993 342479 60134

No. 92-800

Supreme Court, U.S.
FILED
JAN 13 1993
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Petitioner,

v.

KATHLEEN E. LES, *et al.*,

and

WILLIAM K. REILLY, Administrator of the Environmental Protection Agency, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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BRIEF OF THE PRIVATE PARTY RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether the Ninth Circuit correctly held that the Environmental Protection Agency violated section 409 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 348, by refusing to revoke regulations permitting the use of benomyl, mancozeb, phosmet and trifluralin as food additives despite having determined that these substances induce cancer?

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
TABLE OF AUTHORITIES	iii
STATEMENT OF THE CASE	1
REASONS FOR DENYING THE WRIT	4
CONCLUSION	11

TABLE OF AUTHORITIES

FEDERAL CASES — Page

Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) 5
Federal Deposit Ins. Corp. v. Philadelphia Gear Corp., 476 U.S. 426 (1986) 8
Norwegian Nitrogen Products Co. v. United States, 288 U.S. 294 (1933) 8
Public Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988) ..2, 3, 4, 5
United States v. Ewig Bros. Co., 502 F.2d 715 (7th Cir. 1974), *cert. denied*, 420 U.S. 945 (1975) 9
Wisconsin Department of Revenue v. William Wrigley, Jr., Co., —— U.S. ——, 112 S.Ct. 2447 (1992) 4

STATUTES

Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 *et seq.* 5
Federal Food, Drug and Cosmetic Act,
21 U.S.C. § 342(a) 10
21 U.S.C. § 346a(b) 9
21 U.S.C. § 348 ..... 2, 5, 6, 8
21 U.S.C. § 360b 2, 8
21 U.S.C. § 376 ..... 2, 8

MISCELLANEOUS

53 Fed. Reg. 41,104 (Oct. 19, 1988) 3
56 Fed. Reg. 7750 (1991) 3

LEGISLATIVE HISTORY

H.R. Rep. No. 1385, 83rd Cong., 2d Sess. 6-7 (1954), XII *A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments* 838-39 (1979) 10

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BRIEF OF THE PRIVATE PARTY RESPONDENTS IN OPPOSITION *

STATEMENT OF THE CASE

Section 409 of the Federal Food, Drug and Cosmetic Act ("FFDCA") contains a proviso, known as the "Delaney clause," that explicitly mandates that "no

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* The private party respondents are the petitioners in the court below (Kathleen E. Les, Frances Les Thomas, Manuel Jesus Perez Morales, David R. Perez, and Manuel R. Perez) and petitioner-intervenors below (American Federation of Labor and Congress of Industrial Organizations, Natural Resources Defense Council, Inc., and Public Citizen).

[food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal . . . ." 21 U.S.C. § 348(c)(3). For over 25 years, Congress, the courts and the agencies responsible for implementing this clause—and the two parallel clauses regulating animal drugs and color additives (*id.*, §§ 360b(d)(1)(H), 376(b)(5)(B))—have read the statutory language as imposing an *absolute* ban on the use of carcinogens in food additives, color additives or animal drugs.

The Delaney clause's express prohibition on the use of any cancer-inducing food additive reflects Congress' judgment that safe thresholds cannot be established for carcinogenic substances. Over the years, opponents of this "zero-risk" policy have attacked the Delaney clause as overly restrictive, claiming that science is able to set acceptable risk levels. Until recently, however, all parties to the debate have accepted the fundamental premise that any alteration of this policy would require congressional action.

In 1985, the Food and Drug Administration (FDA), embarked upon a short-lived attempt to create a *de minimis* exception to the color additive Delaney clause. That attempt was struck down by the United States Court of Appeals for the District of Columbia Circuit in *Public Citizen v. Young*, 831 F.2d 1108, 1113 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988). The D.C. Circuit affirmed that such an agency-created exception is inconsistent with the statutory language and congressional intent, and that FDA's policy concerns were properly addressed to Congress. In the years since the *Public Citizen* decision, FDA, which has authority not only over color additives but also over all food additives other than pesticides, has made no further attempt to engraft a *de minimis* exception onto any of the three Delaney clause provisions.

Against this background, "[t]he proceedings in this case had their genesis in October 1988 when . . . . [the

Environmental Protection Agency] announced a new interpretation of the Delaney clause . . . ." Pet. App. 5a. EPA declared—thirty years after the clause was enacted and one year after the *Public Citizen* decision was rendered—that food additives containing pesticides that concentrate in processed foods above the levels permitted on raw foods and that had been found to induce cancer would now be permitted "so long as the particular substances posed only a 'de minimis' risk of actually causing cancer." *Id.* (quoting Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41,104, 41,110 (Oct. 19, 1988)).

At the same time, EPA announced that the Agency had determined that certain pesticide chemicals, including the four at issue here—for which EPA had previously issued regulations under the Delaney clause permitting their use as food additives on the ground that the chemicals were *not* carcinogenic—did in fact induce cancer within the meaning of the Delaney clause. *Id.* at 3a (citing 53 Fed. Reg. at 41,119).

Respondents petitioned EPA to revoke the regulations permitting the use of seven cancer-causing substances as food additives. In February, 1991, EPA refused to revoke the regulations for four of these substances, despite its own conclusion that each had been found to induce cancer. Final Order Responding to Objections to EPA's Response to Petition Requesting Revocation of Food Additive Regulations ("Final Order"), 56 Fed. Reg. 7750 (1991), *reprinted at* Pet. App. 12a. Respondents sought review of EPA's Final Order in the United States Court of Appeals for the Ninth Circuit.

The Ninth Circuit set aside EPA's order, finding that:

> the language of the Delaney clause, its history and purpose all reflect that Congress intended the EPA to prohibit *all* [food] additives that are carcinogens, regardless of risk involved.

Pet. App. 2a-3a (emphasis added). The Ninth Circuit subsequently denied EPA's petition for rehearing. On December 16, 1992, EPA informed the Ninth Circuit that it would not be seeking certiorari.

REASONS FOR DENYING THE WRIT

The Ninth Circuit's decision is entirely sound, is consistent with this Court's precedent regarding judicial review of agency action and is not in conflict with the decision of any other circuit. Accordingly, there is no basis for this Court's review, and the *certiorari* petition filed by the National Agricultural Chemicals Association (NACA) should be denied.[1]

1. NACA argues that the Ninth Circuit's "rigid adherence to the literal language of the Delaney clause[] squarely conflicts with the *de minimis* principle of statutory construction repeatedly recognized by this Court." Pet. at 15. According to NACA, there is a general principle that no matter what a statute says, agencies *always* have inherent authority to refrain from regulation of *de minimis* risks. *See* Pet. at 15. There is no such general principle.

In *Wisconsin Department of Revenue v. William Wrigley, Jr., Co.*, 112 S.Ct. 2447 (1992), on which petitioner relies, this Court explained that the *de minimis* principle applies "*absent contrary indication.*" *Id.* at 2458 (emphasis added). Similarly, in *Public Citizen*, the D.C. Circuit, in finding that the color additive Delaney clause prohibited FDA from creating a *de minimis* exception, explained that "the doctrine obviously is not available to thwart a statutory command . . . ." 831 F.2d at 1113.

Here, the Ninth Circuit found such "contrary indication" to a *de minimis* exception in the "clear and mandatory language" of the statute; the "legislative history [which] reflects that Congress intended th[at] very

[1] We note that the government has determined *not* to file a *certiorari* petition seeking review of the decision below and, instead, has filed a brief opposing NACA's *certiorari* petition.

rigidity"; the contemporaneous agency interpretation which "interpreted the clause as removing all agency discretion regarding carcinogens"; and "Congress[']repeated[] ratifi[cation of] a strict interpretation of the Delaney clause." Pet. App. 6a, 8a-9a.[2]

2. NACA argues further that the Ninth Circuit should have deferred to EPA's interpretation of the Delaney clause. But, as this Court has explained, in interpreting a statute, the first question is "whether Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984). Where the intent of Congress is clear, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842. That portion of the *Chevron* rule governs here.

The Delaney clause clearly states that "*no* additive shall be deemed to be safe if it is found to induce cancer . . . ." 21 U.S.C. § 348(c)(3) (emphasis added).

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[2] Petitioner argues further that the Ninth Circuit's decision somehow conflicts with the D.C. Circuit's decision in *Public Citizen*, which held that the virtually identical color additive Delaney clause does not permit a *de minimis* exception, and which did *not* adjudicate the food additive issue resolved by the Ninth Circuit here. Petitioner's argument rests on the proposition that the *Public Citizen* opinion counselled the Ninth Circuit to consider the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq.—which contains a lower standard for the licensing of carcinogenic pesticides—in determining whether there is a *de minimis* exception under § 409 of the FFDCA, a wholly separate Act. *Public Citizen* contains no such suggestion. FIFRA—which NACA describes as "the principal pesticide regulatory statute" (Pet. at 19 (emphasis omitted))—is, moreover, merely the threshold licensing scheme for all pesticides—including rat poison, weed killers and lawn chemicals—regardless of whether the pesticide is used in food products. FIFRA includes no directive, either explicit or implicit, that substances that are licensable under its standard should be exempt from other regulatory schemes, and makes absolutely *no* attempt itself to set safe or appropriate levels of pesticide residues in food.

This unequivocal command—and more unequivocal language is difficult to imagine—is underscored by the overall statutory structure. Section 409 sets out the general safety standard that no regulation permitting use of a food additive shall issue

> if a fair evaluation of the data before the Secretary . . . fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, that *no additive shall be deemed to be safe* if it is found to induce cancer . . . . [21 U.S.C. § 348(c)(3) (emphasis added)]

In evaluating the data for risks other than cancer, the agency is directed to consider "the probable consumption of the additive," "the cumulative effect of such additive in the diet," and other appropriate "safety factors." *Id.* § 348(c)(5). The Delaney clause, however, stands in stark contrast to this general "evaluation of the data . . . under the conditions of use" scheme. *Id.* § 348(c)(3). The Delaney clause, as we have stressed, mandates that once a substance is found to induce cancer, a determination of safety based on probable consumption or cumulative effect cannot suffice.[3]

The legislative history of section 409 is equally unequivocal and confirms the congressional intent that the

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[3] NACA complains that the Ninth Circuit "unjustifiably cited *Public Citizen* . . . as authority for rejection of EPA's *de minimis* interpretation of the food additive Delaney clause." Pet. at 18; *see also id.* at 21 (referring to the court's "misplac[ed] reliance on *Public Citizen*'s color additive findings . . . ."). But, the Ninth Circuit cited *Public Citizen* only to demonstrate that "its reasoning with respect to the *language of the statute* is equally applicable to both Delaney clauses." Pet. App. 7a (emphasis added). And, EPA agrees that "[t]here are no significant differences in the wording of the food additives and color additives Delaney clauses" and thus that "[t]he precise language of the food additives Delaney clause suggests congressional rigidity . . . ." Final Order, Pet. App. 85a.

Delaney clause be construed according to its terms. As the Ninth Circuit explained:

> The food additive Delaney clause was enacted in response to increasing public concern about cancer. It was initially part of a bill, introduced . . . by Congressman Delaney . . . . The bill, intended to ensure that no carcinogens, no matter how small the amount, would be introduced into food, was at least in part a response to a decision by the FDA to allow a known carcinogen, the pesticide Aramite, as an approved food additive . . . . Of the FDA's approval for sale of foods containing small quantities of Aramite, Congressman Delaney stated:
>
> > The part that chemical additives play in the cancer picture may not yet be completely understood, but enough is known to put us on our guard. . . . The precedent established by the Aramite decision has opened the door, even if only a little, to the use of carcinogens in our foods. That door should be slammed shut and locked. That is the purpose of my anti-carcinogen provision.
>
> . . . . The scientific witnesses who testified before Congress [also] stressed that because current scientific techniques could not determine a safe level for carcinogens, all carcinogens should be prohibited. [Pet. App. at 8a-9a (citations omitted).] [4]

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[4] NACA's suggestion that EPA's "new and changed interpretation," offered thirty years after the statute was enacted, should carry greater weight than the contemporaneous construction by the agency initially charged with interpreting the statute turns the applicable principles upside down. It is the Ninth Circuit that put things in their proper order:

> Throughout its 30-year history, the Delaney clause has been interpreted as an absolute bar to all carcinogenic food additives. In 1958, the Department of Health, Education, and Welfare (which would be charged with administering the food additive provisions of the newly enacted Delaney clause) interpreted the clause as removing all agency discretion regarding car-

To be sure, petitioner, while conceding that the "meaning of the Delaney clause may be clear with respect to non-pesticide food additives regulated exclusively under FFDCA," argues that a different rule should apply to pesticide food additives. Pet. at 24. This argument is flatly wrong.

As a threshold matter, section 409 itself does not differentiate between types of food additives, stating simply that "*no* additive shall be deemed to be safe if it is found to induce cancer. . . ." 21 U.S.C. § 348(c)(3) (emphasis added). Thus, NACA's argument must reduce to the contention that Congress either did not intend for pesticide residues that concentrate in processed foods to be treated as food additives, or that Congress intended

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> cinogens. As a contemporaneous agency construction of the statute, this interpretation is entitled to great weight. *See Norwegian Nitrogen Products Co. v. United States*, 288 U.S. 294, 315 (1933). [Pet. App. at 9a (citations to the Final Order and legislative history omitted).]

NACA's objection that this contemporaneous agency construction was made by HEW rather than EPA (*see* Pet. at 25), ignores the undisputed fact that when the Delaney clause was enacted, HEW was the agency charged with administering the FFDCA for all foods, including those containing pesticides, and moreover, that EPA also agreed with this construction from 1970, when EPA was created, until the Agency's abrupt change in October, 1988.

Indeed, as the Ninth Circuit found further,

> Congress has repeatedly ratified a strict interpretation of the Delaney clause by reenacting all three FFDCA provisions which contain Delaney clauses without changing the Agency's interpretation. *See* 21 U.S.C. § 348 (amended 1960, 1962, 1984); 21 U.S.C. § 360b (amended 1988, 1991); 21 U.S.C. § 376 (amended 1960, 1962, 1970, 1976). [Pet. App. at 9a]

As this Court has stated, "[w]hen the statute giving rise to the longstanding interpretation has been reenacted without pertinent change, the congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress." *Federal Deposit Ins. Corp. v. Philadelphia Gear Corp.*, 476 U.S. 426, 437 (1986) (quotation omitted).

that the identical language of section 409 be construed differently for pesticide food additives than for other food additives. Neither of these contentions can withstand a moment's scrutiny.

First, there can be no real dispute that section 409, which includes the food additive Delaney clause, does in fact apply to pesticide residues that concentrate in processed foods. As EPA acknowledged:

> [t]he case of *United States v. Ewig Bros. Co.*, 502 F.2d 715 (7th Cir. 1974), *cert. denied*, 420 U.S. 945 (1975), held that a pesticide chemical in a processed food was a "food additive" regulated by section 409 and this decision is well-supported by the language of the statute and the legislative history on the issue. [Final Order, Pet. App. at 65a-66a.] [5]

Second, petitioner's assumption that because *section 408* contains standards for pesticides in *raw foods*, Congress must also have meant for those same standards to be used under section 409 for regulating pesticides that concentrate in processed foods is directly contradicted by explicit statutory language which mandates the exact relationship between sections 408 and 409.[6] As the Ninth Circuit pointed out:

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[5] Indeed, as the Ninth Circuit pointed out:

> [The] contention that Congress never intended the food additive provision to encompass pesticide residues is belied by the events prompting passage of the provision into law: FDA approval of Aramite was the principal impetus for the food additive Delaney clause and Aramite was itself a regulated pesticide. [Pet. App. at 10a.]

[6] Section 408 allows the agency to establish tolerances or exemptions for certain uses of pesticides on raw agricultural products if such regulations would "protect the public health." 21 U.S.C. § 346a(b). Unlike section 409, section 408 does not contain Delaney clause language explicitly precluding a finding of safety if the substance induces cancer and moreover, also allows the agency to

> [S]ection 402 of the FFDCA, 21 U.S.C. § 342(a)(2)(C), [the "flow-through" provision] expressly harmonizes [section 408] with the Delaney clause by providing that residues on processed foods may not exceed the tolerance level established for the raw food. The statute unambiguously provides that pesticides which concentrate in processed food are to be treated as food additives, and these are governed by the Delaney food additive provision contained in section 409. [Pet. App. 7a-8a; *see also id.* at 4a-5a.]

In sum, NACA's elaborate statutory claim comes down to petitioner "in effect ask[ing the courts] to approve what [EPA] deems to be a more enlightened system than that which Congress established." Pet. App. at 11a. As the Ninth Circuit said in rejecting that re-

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consider the "necessity for the production of an adequate, wholesome, and economical food supply." *Id.* In enacting section 408, Congress did not intend to affect regulation of pesticides in processed foods:

> It is intended . . . to draw a sharp line of distinction between the subjects covered by this bill and the subjects which are unaffected by it. This bill covers the regulation of the residue from pesticide chemicals which may remain in or on food in its raw or natural state as usually purchased by the consumer or the food processor. . . . *This bill does not attempt to regulate the residue from pesticide chemicals which may remain in or on processed, fabricated, or manufactured food other than by limiting the permissible residues on raw agricultural commodities. Food processed by operations such as cooking, freezing, dehydration, or milling would remain subject to [other sections of the FFDCA] rather than being regulated by this bill.* For example, the provisions of this bill would apply to the residue of DDT remaining in or on fresh apples or apples which are washed or waxed for market. The provisions of this bill would not apply to any residue of DDT remaining in or on applejuice or applesauce which may be prepared or produced from such apples. [H.R. Rep. No. 1385, 83rd Cong., 2d Sess. 6-7 (1954), XII *A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments* 838-39 (1979)]

quest, "Revising the existing statutory scheme, however, is neither our function nor the function of the EPA." *Id.*

CONCLUSION

For the reasons stated above, the Petition for a Writ of Certiorari should be denied.

Respectfully submitted,

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Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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PETITIONER'S REPLY

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PETITIONER'S REPLY

I. Federal Respondents' tepid opposition to the certiorari petition not only is unpersuasive, but also completely contradicts the position that EPA and the Justice Department took after the court of appeals rendered its opinion, and reverses the Solicitor General's previous position on Supreme Court review of the important issue in this case.

1. Federal Respondents now assert that this case does not warrant further review, but less than four months ago, they sought and obtained a stay of mandate on the ground that the issues in this case are "of exceptional importance in terms of food safety and are worthy of Supreme Court review." Resp. Motion for Stay of Issuance of Mandate at 5 (filed in *Les v. Reilly*, No. 91-70234) (9th Cir. Oct. 1, 1992)). They argued that

> *EPA has sound legal reasons on which to seek Supreme Court review and the critical impact that the Court's decision will have on the regulation of pesticides in this country makes this case worthy of such review.* Moreover, EPA seeks this stay not for purposes of delay, but to ensure that the important legal issues raised by the panel's decision which may affect dozens of pesticide food uses and the future implementation of FFDCA and [FIFRA], across the country, *are fully and finally resolved in the context of further appellate review* before EPA is required to take action having potentially significant and far-reaching social and economic impacts.

Id. at 2-3 (emphasis added). EPA Administrator Reilly voiced his concern that "[t]he consequences of [the Ninth Circuit's] decision are potentially far-reaching and profound," and urged the Solicitor General to seek review. William K. Reilly, Remarks at the National Agricultural Chemicals Association Annual Meeting 3 (Sept. 28, 1992) (transcript available from EPA Office of Administrator); *Supreme Court Review Needed of Delaney Clause Case, Reilly Tells NACA*, 189 Daily Env't Rep. (BNA) A-7 (Sept. 29, 1992).

The government's refusal to seek certiorari is particularly puzzling in view of the fact that in March 1988 it opposed certiorari in a case involving FDA's *de minimis* exception to the color additive Delaney clause on the ground that this Court should await a case involving pesticide residues and EPA's *de minimis* exception to the food additive Delaney clause. *See* Br. for the Fed. Resp. in Opp. at 9 (filed in *Cosmetic, Toiletry and Fragrance Ass'n v. Public Citizen*, No. 87-1194) (Mar. 1988)). This is that case!

2. Federal Respondents concede in their opposition that they disagree with the Ninth Circuit's decision, but now claim that "the decision below is consistent with the D.C. Circuit's decision in *Public Citizen v. Young*, 831 F.2d 1108 (1987), *cert. denied*, 485 U.S. 1006 (1988)," which involved FDA's *de minimis* exception to the color additive Delaney clause. Br. for the Fed. Resp. in Opp. at 5. Yet, in seeking a stay of mandate they argued that the court of appeals "disregarded the 'virtual[] . . . presumption' in favor of such an exception" set forth in *Public Citizen*. Resp. Motion for Stay at 3; *see also* Resp. Pet. for Reh'g at 8, 11-15 (filed in *Les* Aug. 20, 1992) (arguing at length that the court of appeals erred in its attempt to apply *Public Citizen*'s "extraordinary rigidity" test). Even if, as Federal Respondents now mysteriously and erroneously assert, the Ninth Circuit conducted "the type of analysis that the D.C. Circuit set forth in *Public Citizen*," it was riddled with errors, as Federal Respondents themselves vigorously argued in their petition for rehearing and motion to stay the mandate. Br. for Fed. Resp. at 7; *see* Resp. Pet. for Reh'g; Resp. Motion for Stay at 3-4.

3. Incredibly, Federal Respondents now suggest that "the court of appeals followed the analysis set forth in *Chevron* [*U.S.A. Inc. v. NRDC, Inc.*, 467 U.S. 837, 842-43 (1984)]," and that "it would not have been appropriate under *Chevron* for the court of appeals to have given deference to the agency's interpretation." Br. for Fed. Resp. at 8. In seeking to stay the mandate, however, they emphatically pointed to the Ninth Circuit's deviation from the

principles set forth in *Chevron* as one of the principal reasons why this case warrants Supreme Court review:

> Most importantly, the Court gave no reason whatsoever for *failing to afford appropriate deference* to EPA's statutory interpretation. The Supreme Court might well find that *failure to defer to EPA's construction contravenes principles announced by the Supreme Court in Chevron*. . .

Resp. Motion for Stay at 4 (emphasis added); *see also* Resp. Pet. for Reh'g at 2 ("the Court misapprehended EPA's main argument in support of the reasonableness of the agency's interpretation of the Delaney clause").

4. Federal Respondents now argue that certiorari should be denied because the impact of the Ninth Circuit's decision may be ameliorated if at some point in the future EPA were to change its policy of banning the use of agricultural pesticides which require, but due to the Delaney clause are ineligible to receive, § 409 tolerances. Recognizing the far-reaching consequences of the court's decision, they argued below however, that "[t]he *impact of the panel's decision is potentially so great* that EPA should not have to respond to the mandate *until the Supreme Court has had an opportunity to fully consider and resolve the important legal issues raised by this court's decision.*" Resp. Motion for Stay at 5 (emphasis added). They explained that the Ninth Circuit's opinion will adversely affect availability of numerous pesticides, and that "[t]his may have the effect of increasing the price of food and decreasing overall food safety." *Id.* at 6; *see also* Resp. Pet. for Reh'g at 3 ("the adverse impact of the Court's decision will be felt by consumers and farmers nationwide, as well as by the food and pesticide industries"). The numerous farm, agricultural commodity, food industry, and trade association *amici* supporting the petition have attested to the potentially devastating consequences of the ruling below. Thus, the Solicitor General's speculation regarding the possibility of some future change in policy is not a legitimate basis for denying review of this critically important case.

5. Finally, Federal Respondents assert that "[t]here is no conflict among the circuits on the question presented in the petition." Br. for Fed. Resp. at 5. That is a spurious basis for opposing review here because this is not the type of case which is amenable to consideration by more than one circuit. The Ninth Circuit held that the *de minimis* exception is unlawful; if the court's mandate issues, EPA will have to abandon the *de minimis* exception. As Federal Respondents repeatedly conceded prior to the filing of their opposition, that could have devastating consequences for the American public, agriculture, and the food and pesticide industries. *See* Resp. Motion for Stay at 5-7; Resp. Pet. for Reh'g at 3.

II. The opposition brief filed by the non-government Respondents, a coalition of anti-pesticide groups and individuals, totally ignores the ramifications of the Ninth Circuit's decision and erroneously argues that certiorari should be denied because the court's decision is "entirely sound." Resp. Br. in Opp. at 4. Their principal contention essentially is that the court of appeals was correct because the Delaney clause "says what it says." In other words, according to Respondents, there can be no *de minimis* exception to the Delaney clause or any other statute in the absence of an express provision to that effect. As this Court has recognized, however, federal agencies have *implied* authority to make *de minimis* exceptions, especially with regard to regulation of insignificant health risks, absent contrary indication. *See Wisconsin Department of Revenue v. William Wrigley, Jr., Co.*, 112 S. Ct. 2447, 2458 (1992); *see also Industrial Union Department v. American Petroleum Institute*, 448 U.S. 607, 663-64 (Burger, J., concurring) (citing *Alabama Power Co. v. Costle*, 636 F.2d 323, 360-61 (D.C. Cir. 1980)). In attempting to read such a "contrary indication" into the Delaney clause, it is the Ninth Circuit and Respondents, not Petitioner or EPA, which are attempting to rewrite the statute.

Respondents contend that the court of appeals "found such 'contrary indication' to a *de minimis* exception in the 'clear and mandatory language' of the statute." Resp. Br.

in Opp. at 4 (quoting Pet. App. 6a). That begs the question of whether EPA has *implied* authority to refrain from regulating trivial risks, since the Delaney clause does not include an express prohibition *against* a *de minimis* exception. Respondents also refer to the court's legislative history findings. *Id.* at 4. The court's legislative history analysis, however, was limited to enactment of the Delaney clause itself, and completely overlooked congressional statements surrounding enactment and reenactment of FIFRA, and also § 408, FFDCA's pesticide-specific tolerance provision. *See* Resp. Pet. for Reh'g at 8-10. If the court of appeals (or Respondents) had endeavored to review FIFRA's voluminous legislative history, the stark conflict between a literal interpretation of the Delaney clause and Congress' repeatedly expressed intent to regulate pesticides, including those "taken up in the food chain," pursuant to "a careful balancing of benefits versus risk to determine what is best for man" would have been evident. S. Rep. No. 838, 92d Cong., 2d Sess. 1, 4, *reprinted in* 1972 U.S.C.C.A.N. 3993, 3996. Therefore, a proper *de minimis* analysis would have confirmed that there is nothing in the congressional design for regulating pesticides which provides any indication whatsoever that Congress intended the Delaney clause to be extraordinarily rigid with respect to pesticides which merely pose trivial risks.*

Respectfully submitted,

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* Among the erroneous or misleading contentions in Respondents' Statement of the Case is their notion that EPA has "announced" that certain pesticides, including the four involved in Respondents' administrative petition, "did in fact induce cancer within the meaning of the Delaney clause." Resp. Br. in Opp. at 3.

Supreme Court, U.S.
FILED
FEB 5 1993
OFFICE OF THE CLERK

No. 92-800

IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Petitioner,

v.

KATHLEEN E. LES; FRANCES LES THOMAS;
MANUEL JESUS PEREZ MORALES; DAVID R. PEREZ;
MANUEL R. PEREZ,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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SUPPLEMENT TO PETITIONER'S REPLY

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SUPPLEMENT TO PETITIONER'S REPLY

Pursuant to Rule 15.7, Petitioner wishes to call the Court's attention to the following statement published by Federal Respondents subsequent to the filing of the Solicitor General's brief in opposition:

> The petitioners challenged EPA's February 25, 1991 Final Order in the U.S. Court of Appeals, Ninth Circuit. On July 8, 1992, in *Les v. Reilly*, 968 F.2d 985 (9th Cir.), the court overturned EPA's interpretation that the Delaney clause contains an exception for pesticide uses that present no more than a *de minimis* cancer risk. The court ruled that food additive regulations are barred for any pesticides that are animal or human carcinogens. Although the court's ruling immediately affects only the pesticides involved in the petition, *under the court's interpretation of the Delaney clause, food additive regulations will have to be revoked or denied for dozens of pesticide uses that either have or need such regulations.*
>
> *EPA disagrees with the Ninth Circuit's decision and continues to believe that a de minimis exception is appropriate both as a legal matter and as a matter of public policy. EPA asked the Department of Justice (DOJ) to petition the Supreme Court for a writ of certiorari on behalf of EPA.* The Solicitor General in DOJ makes decisions concerning whether cases involving Federal agencies will be appealed to the Supreme Court. The Solicitor General ultimately decided against

> petitioning the Supreme Court to review this case. The Solicitor General concluded that this case was not one of the small number of Federal cases, from among many presented each year for possible Supreme Court action, that merited a petition for certiorari.
>
> The National Agricultural Chemicals Association (NACA), which intervened in the case supporting EPA's position, has filed a petition with the Supreme Court for a writ of certiorari asking the Supreme Court to overturn the Circuit Court's decision. For the moment, the effect of the Ninth Circuit's decision has been stayed by the filing of NACA's petition with the Supreme Court. EPA does not know when the Supreme Court will rule on NACA's petition. *If the Supreme Court does not agree to hear NACA's petition, or upholds the Ninth Circuit's decision, EPA will be required to revoke the tolerances that were the subject of the California petition. EPA is prepared to act promptly after any adverse Supreme Court action.*

58 Fed. Reg. 7470, 7472 (1993) (emphasis added).[1]

On February 2, 1993, EPA Administrator Browner released lists identifying 35 major agricultural pesticides which may be affected by the Ninth Circuit's ruling. Ms. Browner stated:

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[1] The *Federal Register* notice was signed by former EPA Administrator William K. Reilly on January 19, 1993. On January 29, 1993, it was approved for publication by EPA's new Administrator, Carol M. Browner.

> *EPA does not believe that the pesticides in [these] lists pose an unreasonable risk to public health*, based on available data. . . . Thus, the current debate is *not about health risks*, but about the *legal interpretation of the statute*. However, the Agency does believe that the *impact of the Ninth Circuit Court's decision upon pesticide users and food processors could be substantial.*

Carol M. Browner, Note to Correspondents (Feb. 2, 1993) (emphasis added).

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MOTION FILED
JAN 6 1993

No. 92-800

IN THE
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OCTOBER TERM, 1992

NATIONAL AGRICULTURAL
CHEMICALS ASSOCIATION,

Petitioner,

v.

KATHLEEN E. LES, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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Date: January 8, 1993

IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1992

No. 92-800

NATIONAL AGRICULTURAL
CHEMICAL ASSOCIATION,

Petitioner,

v.

KATHLEEN E. LES, *et al.*,

Respondents.

**On Petition for Writ of Certiorari to
the United States Court of Appeals
for the Ninth Circuit**

MOTION FOR LEAVE TO FILE BRIEF OF THE WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

Pursuant to Rule 37.2 of the Rules of this Court, the Washington Legal Foundation (WLF) respectfully moves for leave to file the attached brief as *amicus curiae* in support of the Petition for a Writ of Certiorari. Counsel for Petitioner has consented to the filing of this brief, as have counsel for the United States and counsel for some of the Respondents. WLF has telephoned and written to counsel for the other Respondents but has been unable to obtain written consent from them. Accordingly, this motion is necessary.

WLF is a nonprofit public interest law and policy center with more than 100,000 members and supporters

nationwide. While WLF engages in litigation and the administrative process in a variety of areas, WLF devotes a substantial portion of its resources to advancing the interests of the free-enterprise system. To that end, WLF has appeared on numerous occasions as *amicus curiae* before the United States Supreme Court as well as other federal and state courts in cases where environmental and public health concerns need to be balanced with steps necessary to maintain a healthy free-enterprise system. *See, e.g., Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476 (1991).

WLF has also been involved on many occasions in litigation involving the proper role of the judiciary in our American system of government. WLF has repeatedly argued in courts at all levels that the judiciary -- as the one unelected branch of government -- should be mindful of its limited role in public policy making. *See, e.g., Lujan v. Defenders of Wildlife*, 112 S. Ct. 2130 (1992); *Lujan v. National Wildlife Federation*, 110 S. Ct. 3177 (1990).

WLF recognizes the importance of ensuring that pesticides used in agricultural production do not end up jeopardizing the safety of the nation's food supply. At the same time, WLF also recognizes that pesticides have played an important role -- and must continue to play an important role -- in ensuring the availability of abundant and wholesome food supplies. WLF believes that EPA in this case has struck a proper balance between these two concerns. Moreover, now that EPA has struck that balance -- and has done so in a manner that is not inconsistent with its mandate from Congress -- the courts should be extremely reluctant to second-guess EPA's decision.

WLF believes that its brief may be of assistance to the Court in deciding the issues raised in this Petition. WLF brings to this case a perspective that differs from that of any of the parties. It has no financial and/or administrative stake in the outcome of this action; it is

filing solely out of a desire to assist the Court in arriving at a proper resolution of the issues raised.

For all the foregoing reasons, *amicus curiae* Washington Legal Foundation respectfully requests that it be allowed to participate in this case by filing the attached brief.

Respectfully submitted,

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January 8, 1992

QUESTION PRESENTED

Does the United States Environmental Protection Agency have authority to establish a "*de minimis*" exception to § 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the "food additive Delaney Clause") to allow use of agricultural pesticides which are carcinogenic in laboratory animals, but pose virtually no risk of cancer to consumers of processed foods?

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

INTERESTS OF *AMICUS CURIAE* 1

PRELIMINARY STATEMENT 1

STATEMENT OF THE CASE 3

REASONS FOR GRANTING THE PETITION . . . 4

I. PROPER RESPECT FOR THE ROLE OF ADMINISTRATIVE BODIES IN OUR SYSTEM OF GOVERNMENT REQUIRES THAT EPA'S DECISION BE AFFIRMED . . . 5

II. EPA EMPLOYED PROPER TECHNIQUES OF STATUTORY CONSTRUCTION IN ANALYZING THE FOOD ADDITIVE DELANEY CLAUSE 11

CONCLUSION 14

TABLE OF AUTHORITIES

Page

Cases:

Alabama Power Co. v. Costle, 636 F.2d 323 (D.C. Cir. 1979) 6
Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) . . . . . *passim*
Pauley v. Bethenergy Mines, Inc., 111 S. Ct. 2524 (1991) 6
Public Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987) 6-8
Rust v. Sullivan, 111 S. Ct. 1759 (1991) 10
Wisconsin Dep't of Revenue v. William Wrigley, Jr., Co., 112 S. Ct. 2447 (1992) 7-8
Wisconsin Public Intervenor v. Mortier, 111 S. Ct. 2476 (1991) 12

Statutes:

Federal Food, Drug, and Cosmetic Act
§ 402(a)(2)(C), 21 U.S.C. § 342(a)(2)(C) 13
§ 408, 21 U.S.C. § 346a 13
§ 409(c)(3)(A), 21 U.S.C. § 348(c)(3)(A) . *passim*
§ 512(d)(1)(H), 21 U.S.C. § 360b(d)(1)(H) . . . 7
§ 706(b)(5)(B), 21 U.S.C. § 376(b)(5)(B) 7

Miscellaneous:

56 Fed. Reg. 7750-7775 (Feb. 15, 1991) . 3, 8, 11, 13

National Research Council, *Regulating Pesticides in Food: The Delaney Paradox* (National Academy Press 1987) 13

G. Nager, *The Supreme Court's 1991 Term: Binding Law by Bureaucracy* (Washington Legal Foundation 1991) 6

Page

L. Silberman, *Chevron -- The Intersection of Law and Policy*, 58 Geo. Wash. L. Rev. 821 (1990) . 10

C. Sunstein, *Law and Administration after Chevron*, 90 Colum. L. Rev. 2071 (1990) 9-10

IN THE
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NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,

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On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

---

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTERESTS OF *AMICUS CURIAE*

The interests of *amicus curiae* Washington Legal Foundation are set out fully in the motion for leave to file accompanying this brief.

PRELIMINARY STATEMENT

Striking the proper balance between, on the one hand, minimizing health risks caused by use of pesticides on our nation's food supply and, on the other hand, ensuring the availability of abundant and wholesome food supplies through the use of pesticides, is an extremely complex task. Congress has addressed that issue in numerous statutes adopted over the past half century.

Nonetheless, given the complexity of the subject matter, it is understandable that Congress has been unable to anticipate and address directly every issue that has arisen in the course of America's effort to achieve the proper balance between the goals cited above. Accordingly, it has been the task of a variety of federal administrative bodies to address the issues not directly addressed by Congress. For example, Congress was silent regarding whether the food additive Delaney Clause in § 409 of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 348, should include a *de minimis* exception such that the presence of pesticides posing trivial cancer risks would not thereby be forbidden in processed foods. Confronted with that silence, EPA (the agency charged with regulating the presence of pesticides in processed foods) responded by announcing that it would interpret the Delaney Clause as including a *de minimis* exception.

Respondents were unhappy with that decision and asked the court below to overturn it; they persuaded the lower court that EPA has no authority to create a *de minimis* exception. Respondents' argument and the lower court's decision misperceive the role of the executive branch in our system of government. The passage of time inevitably discloses gaps in all legislation, and this Court has made clear that it *is* the role of administrators to attempt to fill those gaps. The courts are not authorized to second-guess those attempts when, as here, an administrator's action is reasonable and is not directly contrary to Congress's expressed intent.

If Respondents were unhappy with EPA's decision, they should have asked Congress to overturn the decision through new legislation. But they should not be permitted to invoke the aid of the courts to refight an issue that they lost in the democratically elected branches of government. The Court should grant the Petition for a Writ of Certiorari in order to correct this unwarranted judicial intrusion into the affairs of the executive branch. WLF's

brief focuses on why it is that EPA's decision is entitled to deference and leaves to others a more detailed accounting of the language and legislative history of the food additive Delaney Clause.

STATEMENT OF THE CASE

In the interests of brevity, WLF hereby incorporates by reference the Statement of the Case contained in the Petition for a Writ of Certiorari.

In brief, Respondents in 1989 petitioned EPA to revoke 14 food additive regulations covering seven pesticides; Respondents argued that since EPA had determined that the pesticides were animal carcinogens, the regulations violated the food additive Delaney Clause.[1] EPA granted the petition as to the pesticides dicofol and DDVP; denied the petition as to the pesticide phosmet (because EPA had not definitively determined whether phosmet is a carcinogen); denied the petition as to the pesticide mancozeb (because there is an ongoing Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") proceeding that is addressing regulations concerning the presence of mancozeb in processed foods); and denied the petition as to the pesticides benomyl and trifluralin (because EPA determined that its regulations concerning use of those pesticides result in residues (on processed foods) that pose a *de minimis* cancer risk). *See* 56 Fed. Reg. 7750 (Feb. 25, 1991).[2]

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[1] Before issuing a food additive regulation covering a pesticide, EPA is required by the FFDCA to determine that use of the pesticide "will be safe." FFDCA § 409(c)(3)(A), 21 U.S.C. § 348(c)(3)(A). The food additive Delaney Clause modifies the general safety provision as follows: "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." *Id.*

[2] EPA did not rule on the petition as to the pesticide chlordimeform, because EPA had previously revoked chlordimeform's food additive regulations. *Id.*

Respondents filed a petition in the United States Court of Appeals for the Ninth Circuit on April 15, 1991, challenging EPA's refusal to revoke benomyl, trifluralin, phosmet, and mancozeb regulations. They contended that EPA's action violates the FFDCA's food additive Delaney Clause. Specifically, they contended that the food additive Delaney Clause decrees that there is no "safe" level of a pesticide on processed food once that pesticide has been shown to pose a cancer risk -- no matter how slight the risk.

In a July 8, 1992 decision, the Ninth Circuit granted the petition and set aside EPA's order declining to revoke regulations for the four pesticides at issue. Petition Appendix (Pet. App.) 1a-12a (reported at 968 F.2d 985 (9th Cir. 1992)). The Ninth Circuit held that EPA exceeded its authority in interpreting the food additive Delaney Clause as containing an exception for pesticides that pose a *de minimis* cancer risk. The National Agricultural Chemicals Association (NACA), which had intervened in the Ninth Circuit in support of EPA's order, subsequently filed a Petition for a Writ of Certiorari, seeking review of the Ninth Circuit's decision.

REASONS FOR GRANTING THE PETITION

This case raises an issue of exceptional importance -- the safety of our nation's food supply. Top-ranking EPA officials have acknowledged that the Ninth Circuit's decision -- if allowed to stand -- will have "far-reaching and dramatic impacts on pesticide use in this country" and could result in increased cancer risk to consumers if the pesticides at issue in this case are replaced by approved pesticides that are significantly more carcinogenic. Pet. 12-13.

This case also raises important issues regarding the proper role of the courts in our system of government. Indeed, the crucial nature of the public health issues raised in this case provide particularly compelling grounds for

judicial reluctance to second-guess the views of those government officials assigned the task of safeguarding public health.

Policy choices such as whether to permit pesticides posing trivial cancer risks to be present on processed foods are most appropriately made by the political branches of government. In the absence of a clear directive from Congress on such issues, it up to the executive branch -- not the courts -- to make the required choices. EPA made just such a policy choice in this case when it determined that the food additive Delaney Clause is subject to a *de minimis* exception. It makes no difference whether the courts agree with EPA's policy choice or even whether they believe that Congress would have made the same choice had Congress directly addressed the issue; rather, a proper understanding of the respective roles of the three branches of our government requires that EPA's policy choice be upheld so long as it is a reasonable choice. EPA has demonstrated that its policy choice not only is reasonable but also makes the most sense out of the sometimes-conflicting mass of federal pesticide statutes.

The Ninth Circuit's rejection of EPA's policy choice was founded on its rejection of EPA's argument that the food additive Delaney Clause contains a *de minimis* exception. That decision is contrary to this Court's decisions regarding *de minimis* exceptions and directly conflicts with the reasoning of a decision of the United States Court of Appeals for the District of Columbia Circuit in a case involving a closely analogous statute.

I. PROPER RESPECT FOR THE ROLE OF ADMINISTRATIVE BODIES IN OUR SYSTEM OF GOVERNMENT REQUIRES THAT EPA'S DECISION BE AFFIRMED

Since issuing its landmark decision in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the Court has repeatedly made clear its commitment to limited judicial review of an administrative

agency's implementation of statutes which the agency is charged with implementing. That commitment "reflects a sensitivity to the proper roles of the political and judicial branches." *Pauley v. Bethenergy Mines, Inc.*, 111 S. Ct. 2524, 2534 (1991). As the Court noted in *Chevron*, "[F]ederal judges -- who have no constituency -- have a duty to respect legitimate policy choices made by those who do." *Chevron*, 467 U.S. at 866.

Chevron mandates that courts undertake a two-step process when reviewing agency action that involves interpretation of a federal law which the agency is charged with implementing. First, if Congress has told the agency what to do about the "precise" question at issue through a clear command in a law, the agency must do what Congress has told it to do. *Id.* at 842-43. If not, the court must simply determine whether the agency's interpretation is a reasonable one and, if so, be bound by it. *Id.* at 843. The reviewing court is so bound even if it "would have reached [another result] if the question initially had arisen in a judicial proceeding." *Id.* at 843 n.11. *Chevron* thus vests federal agencies with the power authoritatively to decide what the law is and to create binding interpretations -- and an aggrieved party may be denied all recourse in a court of law. *See* G. Nager, *The Supreme Court's 1991 Term: Binding Law by Bureaucracy* (Washington Legal Foundation 1991).

Chevron dictates that EPA's interpretation of the food additive Delaney Clause be upheld in this case. At issue is whether EPA acted properly in determining that the food additive Delaney Clause contains a *de minimis* exception. The language of the clause is silent regarding whether such an exception exists. Prior to the decision below, the federal courts were generally in agreement that in the absence of strong evidence to the contrary, it can legitimately be inferred that a statute is subject to a *de minimis* exception. *See Public Citizen v. Young*, 831 F.2d 1108, 1113 (D.C. Cir. 1987); *Alabama Power Co. v. Costle*, 636 F.2d 323, 360-61 (D.C. Cir. 1979) ("Unless Congress has been extraordinarily rigid, there is likely a

basis for an implication of *de minimis* authority to provide exemption when the burdens of regulation yield a gain of trivial or no value"). There is no evidence that Congress contemplated "extraordinarily rigid" application of the food additive Delaney Clause, and (applying the second prong of the *Chevron* test) EPA's interpretation of the clause as containing a *de minimis* exception is "reasonable" -- particularly in light of the judicial presumption in favor of such exceptions.

The Ninth Circuit's decision relied on *Public Citizen*, in which the D.C. Circuit ruled that the color additive Delaney Clause, § 706(b)(5)(B) of the FFDCA, 21 U.S.C. § 376(b)(5)(B), is not subject to a *de minimis* exception. Pet. App. 7a.[3] *Public Citizen* provides no support for the decision below and in fact directly conflicts with that decision.

Public Citizen held that a statute should be presumed to provide for a *de minimis* exception in the absence of evidence that Congress has been extraordinarily rigid in adopting the statute.[4] *Public Citizen* found that the color

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[3] There are three anti-cancer "Delaney Clauses" in the FFDCA. The one at issue in *Public Citizen* was the color additive Delaney Clause. At issue in the instant case is the food additive Delaney Clause. The third Delaney Clause (21 U.S.C. § 360b(d)(1)(H)) deals with animal food and drugs. As the D.C. Circuit noted in *Public Citizen*, the three Delaney Clauses "differ slightly in language, *more materially in statutory context and legislative history.*" *Public Citizen*, 831 F.2d at 1109 (emphasis added).

[4] This Court's decision in *Wisconsin Department of Revenue v. William Wrigley, Jr., Co.*, 112 S. Ct. 2447 (1992), is similar. Rejecting an argument that recognition of a *de minimis* exception to a statute violates the maxim that the plain language of a statute ought to control its interpretation, the Court said that the argument:

> [I]gnores the fact that the venerable maxim *de minimis non curat lex* ("the law cares not for trifles") is part of the established background of legal principles *against which all enactments are adopted*, and which all enactments (absent

(continued...)

additive Delaney Clause is not subject to a *de minimis* exception only after finding that Congress had exhibited such rigidity in adopting that particular clause in 1960. *Public Citizen*, 831 F.2d at 1113-17. Given that the *Public Citizen* court looked exclusively at the color additive Delaney Clause's statutory context and legislative history (and not to the clause's wording) in discerning such rigidity, *Public Citizen* does not support Respondents' contention that the similarity in language between the two Delaney Clauses requires a finding that Congress was displaying similar rigidity when it adopted the food additive Delaney Clause in 1958. Indeed, the *Public Citizen* court stressed repeatedly that "the food additive Delaney Clause raise[d] complex issues distinct" from those in *Public Citizen* (*id.* at 1118 n.13) and that its decision should not be viewed as foreordaining a similar interpretation of the food additive Delaney Clause. *Id.* at 1119-20.

In the final order that is the subject of Respondents' challenge, EPA discussed at great length both the statutory context and the legislative history of the food additive Delaney Clause. That discussion (which will not be repeated here) demonstrated that Congress did not clearly express a rigid intent that the clause not be subject to a *de minimis* exception. *See* 56 Fed. Reg. 7758-73. In the absence of a clear expression of such Congressional intent, *Public Citizen* and *Chevron* mandate that this Court defer to EPA's reasonable interpretation of the clause.[5]

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[4] (...continued)
contrary indications) are deemed to accept.

Wisconsin Department of Revenue at 2457.

[5] In at least one respect, Respondents in the court below seriously misconstrued EPA's rationale for its decision: Respondents stated that "EPA argues that a rigid rule against carcinogens need no longer be followed because that rule was based on the state of scientific knowledge in 1958, not 1991." Respondents' Ninth Circuit Brief at 21. EPA has not in these proceedings characterized the food additive (continued...)

The Ninth Circuit noted that EPA's current interpretation of the food additive Delaney Clause differs from previous federal government interpretations of the clause. Pet. App. 9a. Such switches in an agency's interpretation of a statute in no way lessen the deference owed to the agency's current interpretation by virtue of *Chevron*. As the Supreme Court reiterated in a recent decision:

> This Court has rejected the argument that an agency's interpretation "is not entitled to deference because it represents a sharp break with prior interpretation" of the statute in question. *Chevron*, 467 U.S., at 862. In *Chevron*, we held that a revised interpretation deserves deference because "[a]n initial agency interpretation is not instantly carved in stone" and "the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis." *Id.*, at 863-864. An agency is not required to establish rules of conduct to last forever.

Rust v. Sullivan, 111 S. Ct. 1759, 1769 (1991). *See also*, C. Sunstein, *Law and Administration after Chevron*, 90

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[5] (...continued)
Delaney Clause as "a rigid rule against carcinogens." Moreover, the Ninth Circuit (Pet. App. 8a) missed the import of the advances in scientific knowledge between 1958 and 1991. Scientists who testified before Congress regarding the 1958 food additives amendment did not oppose establishing safe dosage levels for carcinogenic food additives because they believed that there was no such thing as a safe dosage of such food additives; rather, they did so because they recognized that scientific knowledge in 1958 was such that scientists were incapable of determining safe dosage levels. 56 Fed. Reg. 7769-70. Nothing in the legislative history of the food additive Delaney Clause suggests that Congress in 1958 intended to prohibit *de minimis* levels of carcinogenic food additives even after scientific knowledge had advanced to the point that scientists could accurately determine what constitutes a *de minimis* level.

Colum. L. Rev. 2071, 2103 (1990) ("Under *Chevron*, agency views receive deference not because they capture a unitary intended meaning, but because the resolution of statutory ambiguities should be undertaken by accountable, specialized administrators, not by courts").

The Ninth Circuit not only declined to defer to EPA's interpretation of the food additive Delaney Clause but actually claimed to be deferring to the prior, contrary federal government interpretations. Pet. App. 9a ("As a contemporaneous agency construction of the statute, [the prior] interpretation is entitled to great weight"). The Ninth Circuit's decision to accord greater weight to a 1958 federal agency interpretation of the food additive Delaney Clause than to EPA's current interpretation is in direct conflict with *Chevron*.

The decision in this case will have enormous consequences for the future of food production in this country; moreover, the proper role of pesticides in food production is a politically divisive issue. The practical and political significance of this case underscores the advisability of courts being reluctant to overturn an agency's interpretation of a statute it is charged with implementing. As Judge Lawrence Silberman has pointed out, "The agencies -- even the independent ones -- have superior political standing to the life-tenured federal judiciary in performing that policy making function." Silberman, *Chevron -- The Intersection of Law & Policy*, 58 Geo. Wash. L. Rev. 821, 823 (1990). WLF believes that a Congressional intent to create a *de minimis* exception to the food additive Delaney Clause can fairly be implied from the clause's statutory framework and legislative history; but even if a court believes otherwise, *Chevron* dictates that EPA's interpretation of the clause be upheld in the absence of evidence of a clear directive from Congress that no such exception is permissible. The Court should grant the Petition in order to correct the Ninth Circuit's improper intrusion into the realm of policy-making.

II. EPA EMPLOYED PROPER TECHNIQUES OF STATUTORY CONSTRUCTION IN ANALYZING THE FOOD ADDITIVE DELANEY CLAUSE

Respondents contended below (and the Ninth Circuit concurred) that EPA arrived at its conclusions concerning the meaning of the food additive Delaney Clause by use of faulty statutory construction techniques. Several of the points raised by Respondents and the Ninth Circuit in this regard merit response.

First, Respondents contended that the effect of EPA's construction of the food additive Delaney Clause is to write that clause out of the FFDCA; Respondents contended that that construction violates a "fundamental rule of statutory construction" by "failing to give effect to every word Congress used." Resp.'s Ninth Circuit Brief at 17. That objection is without merit. In the absence of the Delaney Clause, the FFDCA would permit any level of a carcinogenic pesticide in processed food that EPA considered to be "safe"; EPA's current interpretation of the food additive Delaney Clause condones the presence of carcinogenic pesticides in pesticides only where the risk posed by such pesticides is trivial or *de minimis*. That potentially is a far tougher standard than a mere "safe" standard. In the context of this case, EPA has interpreted a "trivial" risk as a risk of less than one additional cancer case for every one million people every 70 years. *See* 56 Fed. Reg. at 7755-58. That EPA's interpretation of the food additive Delaney Clause does not write the clause out of the FFDCA is underscored by EPA's granting of Respondents' request that it revoke food additive regulations relating to the pesticides dicofol and DDVP. EPA revoked those regulations because it had received inadequate assurances that the cancer risks posed by dicofol and DDVP were *de minimis*; EPA did so despite evidence that those cancer risks were extremely small. *See* 56 Fed. Reg. at 7774-75.

Second, Respondents argued and the Ninth Circuit held that various post-1958 actions undertaken by Congress

constituted congressional ratification of a zero-tolerance interpretation of the food additive Delaney Clause. Resp.'s Ninth Circuit Brief at 23-33; Pet. App. 9a. WLF takes issue with the conclusions drawn by Respondents regarding the various post-1958 actions they cited[6] and further notes the skepticism with which recent Supreme Court decisions have greeted any and all attempts to discern the meaning of a statute from post-enactment congressional conduct. *See, e.g., Wisconsin Public Intervenor v. Mortier*, 111 S.Ct. 2476, 2487-91 (1991)(Scalia, J., concurring in the judgment).

Moreover, the Ninth Circuit's and Respondents' entire discussion of post-enactment congressional conduct fails to take account of the strict demands of *Chevron*. In order to overturn EPA's decision, the Ninth Circuit is required by *Chevron* to do more than cite snippets of legislative history that, when taken together, make out a plausible case for its interpretation of the food additive Delaney Clause. Rather, the Ninth Circuit must show that EPA's interpretation of the clause is contrary to a clear congressional directive. *Chevron*, 467 U.S. at 842-43. Rarely, if ever (and certainly not in this case), could

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[6] For example, Respondents contended that Congress's 1977 adoption of legislation providing an exception for saccharin from the requirements of § 409 of the FFDCA (in order to allow the continued use of saccharin as a food additive despite its known carcinogenic qualities) demonstrates that Congress viewed the food additive Delaney Clause as a zero-tolerance provision that did not incorporate a *de minimis* exception. Resp.'s Ninth Circuit Brief at 31-33. WLF takes issue with Respondents' view of history. Indeed, as Respondents themselves concede (*id.* at 31), the FDA in 1977 was preparing to ban saccharin based primarily on the general safety requirement of § 409; accordingly, if the 1977 Congress had believed that the food additive Delaney Clause contained a *de minimis* exception (or, as is more likely, if Congress in 1977 never gave any thought one way or the other to whether a *de minimis* exception existed), it could only have overturned the FDA's proposed action by acting as it did, *i.e.*, by adopting legislation that granted an exception for saccharin from the requirements of § 409 of the FFDCA. Therefore, Congress's adoption of the saccharin exception sheds no light on Congress's views regarding the *de minimis* exception issue.

evidence of post-enactment congressional conduct supply the clear congressional directive required by *Chevron*.

Finally, the Ninth Circuit's decision fails to come to grips with the "Delaney Paradox" described at length by EPA in its order. The Ninth Circuit's interpretation of the food additive Delaney Clause would mean that: (1) Congress intended a zero tolerance for carcinogenic pesticides in processed foods even though they are tolerated on *raw* foods under § 408 of the FFDCA, 21 U.S.C. § 346a; and (2) because pesticide residues on processed foods are acceptable (under § 402(a)(2)(C) of the FFDCA, 21 U.S.C. § 342(a)(2)(C)) if they do not exceed residue levels tolerated on raw foods, Congress intended applicability of the zero-tolerance food additive Delaney Clause to depend solely on whether the pesticide in question tends to increase in concentration during processing. *See* 56 Fed. Reg. 7751-52.

There simply is no scientific basis for distinguishing among carcinogenic pesticides based on whether the pesticides concentrate during food processing; there is no correlation between the tendency of a pesticide to concentrate during food processing and the risk it poses to humans, and thus enforcement of the food additive Delaney Clause on a zero-tolerance basis could lead to increased use of less-safe pesticides simply because they do not tend to concentrate during food processing. *Id.*[7] Accepted rules of statutory construction weigh against ascribing such an irrational intent to Congress in adopting the food additive Delaney Clause. Much of the

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[7] Moreover, ascribing a strict, zero-tolerance meaning to the food additive Delaney Clause would do little to reduce the quantity of carcinogenic pesticides in the typical American's diet. One study concluded that pesticides currently tolerated on processed foods whose use would be affected by zero-tolerance enforcement of the food additive Delaney Clause account for no more than 20% of the typical American's cancer risk arising due to the presence of carcinogenic pesticides on food. National Research Council, *Regulating Pesticides in Food: The Delaney Paradox* at 5 (National Academy Press 1987).

inconsistency among federal statutes governing pesticides is eliminated if the food additive Delaney Clause is determined to include a *de minimis* exception.

In sum, EPA's determination that the food additive Delaney Clause includes a *de minimis* exception is the most natural reading of that clause, taking into account the language of the clause, its legislative history, and its statutory framework. When one adds to that conclusion *Chevron*'s directives, the case for upholding EPA's determination is overwhelming. The Court should grant the Petition in order to overturn the Ninth Circuit's significant departure from accepted rules of statutory construction.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Petition for a Writ of Certiorari be granted.

Respectfully submitted,

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January 8, 1993

MOTION FILED
JAN 13 1993

No. 92-800

IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Petitioner,

v.

KATHLEEN E. LES; FRANCES LES THOMAS;
MANUEL JESUS PEREZ MORALES; DAVID R. PEREZ;
MANUEL R. PEREZ,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* AND BRIEF *AMICUS CURIAE* OF THE AMERICAN FARM BUREAU FEDERATION IN SUPPORT OF PETITIONER

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On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* OF THE AMERICAN FARM BUREAU FEDERATION

The American Farm Bureau Federation respectfully moves for leave to file the attached brief *amicus curiae*, pursuant to Supreme Court Rule 37. Consents from Petitioners and Respondent United States are attached hereto. Consent was refused from individual and organizational respondents.

MOTION OF AMICUS CURIAE

The American Farm Bureau Federation (AFBF) is a not-for-profit, voluntary, general farm organization incorporated under the laws of the State of Illinois. Its purposes are to promote, protect and represent the economic, social and educational interests of farmers and ranchers across the United States. The largest general farm organization in the country, AFBF has member state organizations in all 50 states and Puerto Rico, representing the interests of more than 4 million member families.

Farm Bureau members have a direct and vital interest in the outcome of this case. Federally registered pesticides play an important and integral role in production agriculture by protecting crops from damage or destruction caused by pests and weeds. Nearly all of the fungicides necessary to keep these commodities disease-free will be canceled as a result of the Ninth Circuit's rigid application of the Delaney Clause. The loss of these and other registered products will have a substantial adverse economic impact on growers of agricultural commodities, especially those who produce fruits and vegetables. Many of these growers—Farm Bureau members—will be forced out of business if the means to protect their growing crops are taken away from them.

At the same time, Farm Bureau recognizes that the use of registered products cannot and must not compromise the quality or the safety of the good that is produced.

The decision below threatens both of these interests. Failure to consider the negligible degree of risk of certain pesticides will result in the loss of many pesticides that are necessary for crop protection. Furthermore, due to the unique place occupied by the Delaney Clause in the scheme of pesticide regulation, its strict application could actually result in the use of products that pose a

greater threat of cancer. That is due in part to the fact that pesticides that do not concentrate in processed foods and which do not come under the Delaney Clause might be more harmful than those which do come under it. Also, the failure to consider the degree of risk has prevented the registration of safer, lower risk pesticides and discouraged the production of others.

WHEREFORE, Applicant American Farm Bureau Federation respectfully prays that its Motion for Leave to file the attached Brief *Amicus Curiae* in favor of the Writ of Certiorari be granted.

Respectfully submitted,

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
INTEREST OF *AMICUS CURIAE*	1
WHY THE WRIT SHOULD BE GRANTED	3
I. THE NINTH CIRCUIT'S RIGID INTERPRETATION OF THE DELANEY CLAUSE IS INCONSISTENT WITH THE STATUTORY SCHEME OF PESTICIDE REGULATION AND HINDERS THE ENVIRONMENTAL PROTECTION AGENCY IN THE PERFORMANCE OF ITS PESTICIDE REGULATORY MISSION	4
II. MODERN TECHNOLOGY AND SCIENTIFIC ADVANCES HAVE MADE RIGID ADHERENCE TO THE DELANEY CLAUSE UNNECESSARY	6
III. THE NINTH CIRCUIT'S RIGID APPLICATION OF THE DELANEY CLAUSE WILL HAVE SERIOUS ADVERSE CONSEQUENCES TO OUR NATION'S FOOD PRODUCTION	9
IV. THE DE MINIMIS INTERPRETATION OF THE DELANEY CLAUSE BY EPA IS A REASONABLE REGULATORY RESPONSE	11
CONCLUSION	14

TABLE OF AUTHORITIES

CASES — Page

Public Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987) 3, 13

Defenders of Wildlife v. Administrator, 882 F.2d 1294 (8th Cir. 1989) 4

Wisconsin Department of Revenue v. Wrigley, 112 S.Ct. 2447 (1992) 12

Alabama Power Co. v. Costle, 636 F.2d 323 (D.C. Cir. 1980) 12

STATUTES

Federal Insecticide, Fungicide and Rodenticide Act

7 U.S.C. 136a(5) 4

7 U.S.C. 136d(b) 4

7 U.S.C. 136(bb) 4

Federal Food, Drug and Cosmetic Act

21 U.S.C. 348(c)(3)(A) 3

21 U.S.C. 346a 5

21 U.S.C. 346b 5

21 U.S.C. 348 5

21 U.S.C. 348(c)(3)(A) 5

40 C.F.R. 152.112(g) 6

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On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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BRIEF *AMICUS CURIAE* OF THE AMERICAN FARM BUREAU FEDERATION IN SUPPORT OF PETITIONER

INTEREST OF AMICUS CURIAE

The American Farm Bureau Federation (AFBF) is a not-for-profit, voluntary, general farm organization incorporated under the laws of the State of Illinois. Its purposes are to promote, protect and represent the economic, social and educational interests of farmers and ranchers across the United States. The largest general

farm organization in the country, AFBF has member state organizations in all 50 states and Puerto Rico, representing the interests of more than 4 million member families.

Farm Bureau members have a direct and vital interest in the outcome of this case. Federally registered pesticides play an important and integral role in production agriculture by protecting crops from damage or destruction caused by pests and weeds. At the same time, Farm Bureau recognizes that the use of registered products cannot and must not compromise the quality or the safety of the food that is produced.

The decision below threatens both of these interests. Failure to consider the negligible degree of risk of certain pesticides will result in the loss of many pesticides that are necessary for crop protection. Furthermore, due to the unique place occupied by the Delaney Clause in the scheme of pesticide regulation, the strict interpretation by the Ninth Circuit could actually result in the use of products that pose a greater threat of cancer. That is due in part to the fact that pesticides that do not concentrate in processed foods and which do not come under the Delaney Clause might pose a greater risk than those which do come under it.[1] Also, the failure to consider the degree of risk has prevented the registration of safer, lower risk pesticides and discouraged the production of others.

Through the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food Drug and Cosmetic Act (FFDCA), Congress has accommodated the need for pesticide products in the production of food and the concerns over food safety by enacting a regulatory scheme that balances the benefits of use of the product with the potential risks. When it was enacted, the De-

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[1] *Regulating Pesticides in Food: The Delaney Paradox*, National Academy Press, 1987 p. 85.

laney Clause was a powerful reinforcement of that balance. However, a much better understanding of cancer and its risks, combined with an exponential increase in the ability to detect traces of a substance to the lowest levels during the intervening 35 years has radically changed the place of the Delaney Clause in this balancing scheme. Instead of reinforcing that balance, it now obstructs it.

WHY THE WRIT SHOULD BE GRANTED

This case presents an important issue: how does a federal agency perform its regulatory mission when faced with a legislative provision that conflicts with the rest of an overall regulatory scheme and which has become inconsistent with the intent of Congress? The Ninth Circuit said that the language must be blindly followed, regardless of its effect.

We submit that federal agencies should be accorded some flexibility to consider advancements in science and technology in its administrative and rule-making processes. "Courts (and agencies) are not, of course, helpless slaves to literalism." *Public Citizen v. Young*, 831 F.2d 1108, 1112 (D.C. Cir. 1987). A *de minimis* interpretation provides that flexibility without compromising the regulatory mission of the agency. In this case, the issue is all the more important because the regulatory provision at issue has not only become outdated, but its age has made it inconsistent with the rest of the regulatory statute of which it is a part. Hanging in the balance is the fate of a number of widely used and safe pesticides which are necessary for farmers and ranchers to produce an economically viable crop.

Specifically at issue in this case is the Delaney Clause, codified at section 409 of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 348(c)(3)(A)]. The Food, Drug and Cosmetic Act (FFDCA) together with the Federal Insecticide, Fungicide and Rodenticide Act

(FIFRA) provide the statutory basis for the regulation of pesticides in the United States.

I. THE NINTH CIRCUIT'S RIGID INTERPRETATION OF THE DELANEY CLAUSE IS INCONSISTENT WITH THE STATUTORY SCHEME OF PESTICIDE REGULATION AND HINDERS THE ENVIRONMENTAL PROTECTION AGENCY IN THE PERFORMANCE OF ITS PESTICIDE REGULATORY MISSION.

"Congress enacted the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to regulate the use of pesticides in this country." *Defenders of Wildlife v. Administrator*, 882 F.2d 1294 (8th Cir. 1989). Of primary interest here is the fact that FIFRA regulates the registration, use, labeling and cancellation of pesticides in the United States.

FIFRA provides a balancing test in the registration and cancellation of pesticides. A pesticide will be registered if "it will perform its intended function without unreasonable adverse effects on the environment." 7 U.S.C. 136a(5). Similarly, the Administrator of EPA may cancel a pesticide use if he determines that the pesticide "when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." 7 U.S.C. 136d(b). "Unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(bb). In both cases, therefore, the benefits of a pesticide are weighed against the possible risks to determine whether a pesticide should be registered or canceled.

Where FIFRA directly regulates pesticides through functions such as registration and cancellation, FFDCA regulates pesticides in a more indirect way. It provides

for the establishment of maximum concentrations of pesticide residues ("tolerances") in both raw agricultural commodities and in processed foods. The Environmental Protection Agency (EPA) has the responsibility for establishing and administering these tolerances under FFDCA.

Section 408 of the FFDCA [21 U.S.C. 346a] governs the establishment of tolerances for pesticide residues on raw agricultural commodities. Raw agricultural commodities containing pesticide residues that either exceed the established tolerance, or for which no tolerance has been set, are deemed "adulterated" under the FFDCA and are subject to seizure. Section 408 requires that these tolerances be set at levels deemed necessary to protect public health, while at the same time considering the need for "an adequate, wholesome, and economical food supply." (21 U.S.C. 346b). Like FIFRA, section 408 explicitly provides for the consideration of both the risks and the benefits of a particular pesticide in the setting of tolerances.

Section 409 of FFDCA [21 U.S.C. 348] governs the establishment of tolerances on certain processed foods, and contains the Delaney Clause which is at issue in this case. Section 409 provides tolerances for "food additives," and does not directly mention pesticide residues. The Delaney Clause [21 U.S.C. 348(c)(3)(A)] provides that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." Unlike the registration/cancellation provisions of FIFRA and FFDCA section 408 described above, section 409 strictly applied, does not allow the balancing of risks and benefits in deciding whether or not to issue a tolerance.

Of the major pesticide regulatory provisions, only section 409 with the Delaney Clause employs an absolute

standard rather than a balancing of risks and benefits. Thus, pesticides that pass all the registration criteria of FIFRA and the criteria for obtaining a tolerance under section 408, might be denied a section 409 tolerance on processed foods as a result of the strict application of the Delaney Clause.

But that is not the end of the internal inconsistencies caused by the Delaney Clause. EPA regulations provide that EPA will not register a pesticide for raw agricultural commodities if a section 409 tolerance is required but cannot be obtained because of the Delaney Clause [40 CFR 152.112(g)]. Presumably, if pesticides are later found to induce cancer in humans or in animals they would lose any section 409 tolerance, which would result in the cancellation of the product.

This application of Delaney goes beyond mere inconsistency. It subverts the entire foundation of the pesticide registration/cancellation system established in FIFRA, and also completely undercuts the procedure by which section 408 tolerances are established. In the process, this interpretation of Delaney has ignored the intent of Congress as expressed in both FIFRA and section 408 of the FFDCA.

II. MODERN TECHNOLOGY AND SCIENTIFIC ADVANCES HAVE MADE RIGID ADHERENCE TO THE DELANEY CLAUSE UNNECESSARY.

The swift emergence of new technology and advances in science, when combined with the inherent conflict of Delaney with the pesticide regulatory framework, makes the Ninth Circuit's interpretation of Delaney both inconsistent and counter-productive.

The food additive Delaney Clause was enacted in 1958 —almost thirty-five years ago. Much has changed on the scientific landscape since then. In 1958, scientists were able to detect substances only down to parts per million. Today, substances can be measured at one part per trillion, or lower. Such technological advances have made

a tremendous difference in how risks are assessed and measured. Substances found at levels of parts per million might pose significant health risks to humans or animals, while the same substances found at parts per trillion may pose only a very slight health risk or none at all.

Not only does this modern technology allow the detection of much greater numbers of substances in much smaller amounts, it also permits EPA to assess risks to a much more sophisticated degree. Thus, EPA is now able to determine that certain risks are either "negligible" or "significant," where, as in the past, these risks could not be differentiated. To show how much has changed since the Delaney Clause was enacted, the entire discussion of *de minimis* risks could not have taken place in 1958 because science had not yet been able to define *de minimis* risks in this context. The science of risk assessment itself has undergone significant change in the past several years, which also is enough to justify regulatory flexibility in interpreting the Delaney Clause.

In today's world, the Ninth Circuit's strict interpretation of the Delaney Clause has potentially negative impacts on the food supply and on human health. The Ninth Circuit's interpretation of the Delaney Clause prevents the registration of new, less oncogenic pesticides in favor of pesticides in use before 1978 and which, by EPA comparison, are more toxic. These older pesticides were subject to less stringent testing requirements for registration, a condition which changed in 1978.[2] The National Research Council estimates that more than 80% of the risk of cancer from processed foods comes from pesticides with tolerances granted prior to 1978.[3] Research into newer, safer pesticides that pose very minimal

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[2] *Regulating Pesticides in Food: The Delaney Paradox*, National Academy Press, 1987 p. 85.

[3] *Id.*

risks of cancer are being discouraged by strict application of the Delaney Clause.

Another factor, reflecting the inherent inconsistency between section 408 and 409, causes unintended adverse effects as a result of the Ninth Circuit's interpretation of the Delaney Clause. Processed foods with pesticide residue levels at the same or lower levels as the same section 408 tolerance for raw agricultural commodities are exempt from section 409 tolerances. FFDCA section 402 (a) (2) (C) provides this exemption on the theory that if such residues are safe for raw commodities under section 408, they are also safe in processed foods. Section 409 and the Delaney Clause only involve pesticides which concentrate in processed foods to a degree greater than on raw commodities.

This means that the critical factor for determining section 409 tolerances is not the safety of the pesticide, but whether or not it concentrates in processed foods. Pesticide residues with section 408 tolerances that might induce cancers are nevertheless free of section 409 tolerance requirements if the residues do not concentrate in processed foods.

The Ninth Circuit's view of the Delaney Clause in today's technology would subvert the real purpose of the FFDCA and the original purpose of the Delaney Clause itself. It permits older pesticides to remain on the market at the expense of newer, safer pesticides. More importantly, it discourages research and development of newer, safer pesticides that might not pass the strict zero-risk criterion of the Delaney Clause. All of these factors make it more difficult for EPA and the Food and Drug Administration to carry out their mission to ensure a safe food supply. By contrast, the *de minimis* interpretation advanced by EPA is a reasonable response to the new challenges brought on by this new science. It allows EPA to take advantage of the new technology to more responsibly perform its regulatory mission.

III. THE NINTH CIRCUIT'S RIGID APPLICATION OF THE DELANEY CLAUSE WILL HAVE SERIOUS ADVERSE CONSEQUENCES TO OUR NATION'S FOOD PRODUCTION.

The Ninth Circuit strict application of the Delaney Clause will result in the loss of many pesticides that are necessary for the production of certain crops. The impacts are most likely to be felt during the re-registration process when EPA requires updated data about these pesticides.

EPA contends that section 408 tolerances for fresh agricultural commodities are tied to section 409 tolerances and the Delaney Clause for processed foods. Thus, both commodities produced for the fresh market as well as for processing will be heavily impacted by the Ninth Circuit decision.

Hardest hit will be the so-called "minor use crops," which are typically grown on limited acreage and have a limited market. This category includes all fruits and vegetables, which comprise about 20% of the diets of American consumers. These commodities are vital nutritional components of a person's diet. Study after study has revealed that a diet rich in fruit and vegetables can reduce the risk of heart disease, cancer, and obesity.[4]

The limited market for these pesticides already makes it unattractive for pesticide manufacturers to incur the cost of registration or re-registration of products where the profits are limited. The present suit involves only four products. There are, however, more than 50 widely used products which show some evidence of carciongenicity that will be affected if the Ninth Circuit decision stands.

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[4] "Eat Vegetables for Health's Sake," *American Vegetable Grower* Magazine, Winter 1991 Special Issue, p. 16. It is ironic that a statute designed to prevent the spread of cancer might result in the loss of production of the food products that, when eaten, are most effective in reducing the risk of cancer.

Since many fruits and vegetables are processed as well as fresh, they come under section 409 and the Delaney Clause. Most fungicides used in the production of these crops would be canceled under the decision below, and their loss would result in serious adverse impacts to the growing of fruits and vegetables. Fungicides are necessary to control disease on fruits and vegetables, especially in warm, wet growing areas of the country. The impacts would be most dramatic and severe for fruits and vegetables produced east of the Mississippi River, where temperatures, rainfall and humidity are all high. Florida is the nation's second largest fruit and vegetable producer, and would be hardest hit by the loss of these products. Michigan and Wisconsin are two other major producing states that will be adversely impacted as well.

Without denfiing what it means by carcinogenicity or how it arrived at its conclusions, EPA has alleged that the five most widely used fungicides on fruits and vegetables (Captan, Chlorothanonil, Benomyl, Mancozeb and Maneb) all show some evidence of carcinogenicity.[5] Their loss would especially adversely impact the growing of potatoes, apples, peaches and tree fruits.

In many cases, there are no available alternatives to prevent disease on commodities like cranberries, asparagus and rhubarb.

Two major insecticides—Phosmet and Azinphos-methyl —heavily used on fruits and vegetagles would also be lost if the decision is allowed to stand.

Even if only section 409 tolerances are affected, there will still be major agricultural repercussions. Many growers, especially in California, grow exclusively for processors under contract, and they would be forced out of business by the Ninth Circuit decision. The same circumstances would apply, for example, to producers of

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[5] 53 Red. Reg. 41104 (Oct. 19, 1988).

corn in Wisconsin and Minnesota who also grow under contract. Without the necessary chemicals, these crops would not pass quality or mold standards, and their introduction in the food supply would result in less safe food. Most of this production would move outside the United States and return in processed form. This would serve to further weaken our balance of trade and our position within the world economy.

The fresh market would also be affected under this scenario. Currently, most fresh fruits and vegetables that do not meet fresh standards are processed. Elimination of the section 409 tolerances for the pesticides at issue would also eliminate this practice, making it much more difficult for producers to dispose of such products. Consumers will not accept fruits and vegetables that are bruised, misshapen or damaged. Yet the products at issue here are the very tools to prevent those situations from happening.

There is little likelihood that there will be any alternatives or replacements for those canceled fungicides under current regulatory conditions. Manufacturers, already inhibited from investing large sums of money into research and development for pesticides on minor use crops, will be even less likely to invest money necessary to obtain a registration if registration will be precluded by the decision below.

IV. THE DE MINIMIS INTERPRETATION OF THE DELANEY CLAUSE BY EPA IS A REASONABLE REGULATORY RESPONSE.

In light of the fact that internal legislative inconsistencies and modern science has put the Delaney Clause at odds with the goal of maintenance of the safest food supply possible, EPA adopted its *de minimis* interpretation of the Delaney Clause.

The Court has recently reaffirmed its acceptance of *de minimis* exceptions to seemingly-absolute statutory pro-

visions in *Wisconsin Department of Revenue v. Wrigley*, 112 S.Ct. 2447 (1992). This standard allows some reasonable exceptions to a statute which "operates in such stark, all-or-nothing fashion." *Id.* at 2458. This principle is as applicable to the "stark, all-or-nothing" language of the Delaney Clause as it was to section 381 of the Internal Revenue Code in *Wrigley*.

Adoption of a *de minimis* standard is especially appropriate where, as here, the statutory provision is inconsistent with the rest of the regulatory program. Thus, "notwithstanding the 'plain meaning' of a statute, a court must look beyond the words to the purpose of the act where its literal terms lead to 'absurd or futile results.'" *Alabama Power Co. v. Costle*, 636 F.2d 323, 360 (D.C. Cir. 1980). "Imposition of pointless burdens of regulated entities is obviously to be avoided if possible." *Id.* p. 360-361.

As indicated above, the Ninth Circuit's reading of the Delaney Clause could lead to "absurd or futile results." Pesticides that do not concentrate in processed foods that pose a greater cancer risk will be forced to be used in place of pesticides that concentrate in processed foods and which have a slight or negligible risk of cancer. Pesticides registered prior to 1978 will be prefererd over subsequently registered pesticides, even though the latter pesticides pose less of a risk. This leads to the "absurd result" that cancer risks would be greater by application of the very provision whose purpose it was to prevent concer in foods. Adoption of a *de minimis* interpretation was necessary to bridge the growing gulf between the intent of the regulatory scheme and the original Delaney Clause and to bring them into harmony.

A *de minimis* interpretation reduces these conflicts, permits EPA to perform its regulatory mission in a systematic manner, and protects both the safety of American grown food supplies and the economic viability of agricultural production.

But the Ninth Circuit never addressed the question whether the *de minimis* doctrine as applied to the Delaney Clause was reasonable. Instead the court became one of those "helpless slaves of literalism" that ducked an important health issue. In so doing, the Ninth Circuit erroneously invoked the holding in *Public Citizen v. Young, supra,* to justify its result that the *de minimis* doctrine did not apply in this case.

Public Citizen interpreted a provision similiar to the food additive Delaney Clause—the color additive Delaney Clause (21 U.S.C. 376). The D.C. Circuit determined that the rigid language of that clause did not permit a *de minimis* interpretation. While this is the same result as that arrived at by the Ninth Circuit, the anlysis used in *Public Citizen* might have produced a different result in this case. In fact *Public Citizen* expressly states that "Although the two clauses have almost identical wording, the context is clearly different." *Public Citizen, supra* at 1120. As a result, the D.C. Circuit said that for the issues decided by the Ninth Circuit, "their answer is not foreordained by our decision here." *Id.* at 1120.

For the D.C. Circuit, the difference between the two provisions seems to be the differnce supply in importance between color additives and food additives such as pesticides. The court examined the legislative history of the color additive provision, and concluded that:

> there is evidence that Congress thought the public could get along without carcinogenic colors, especially in view of the existence of safer substitutes. Thus the legislators may have estimated the costs of an overly protective rule as trivial.[6]

The perception of the food additive Delaney Clause by the court was quite different, saying: "Without having canvassed the legislative history of the food additive Delaney Clause, we may safely say that its proponents

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[6] *Public Citizen, supra* at 1117.

could not have regarded as trivial the social cost of banning those parts of the American diet that CTFA argues are at risk." *Public Citizen, supra*, at 1120.

In a sense, the court in *Public Citizen* performed a quick risk/benefit analysis to determine the possible costs resulting from a strict interpretation of the color additive Delaney Clause. Finding that Congress perceived little cost, it held that strict interpretation was meant.

No such analysis or examination of legislative history was performed by the Ninth Circuit. At stake here is the viability of more than 20% of the diet of most Americans, including most of the sources of Vitamin C and beta-kerotene. We submit that this issue is deserving of at least the same type of analysis applied in *Public Citizen*, as to whether a *de minimis* interpretation to the food additive Delaney Clause is a reasonable response to the protection of the health of consumers and the safety of America's food supply.

CONCLUSION

Advancements in science and new technology have reduced the utility and effectiveness of the food additive Delaney Clause within the overall pesticide regulatory framework. Indeed, the Ninth Circuit's interpretation of the Delaney Clause is actually counter-productive to the regulatory mission of EPA and FDA to assure a safe and healthy food supply. The Delaney Clause favors older, more toxic pesticides and those that do not concentrate in processed foods over newer and safer pesticides. In addition, the Ninth Circuit's interpretation of the Delaney Clause threatens the viability of the foods that are most effective in reducing cancer risks.

All of these factors hamper the efforts of EPA and FDA to perform their regulatory functions. In an effort to harmonize the Delaney Clause with the pesticide regulatory framework, the EPA, consistent with accepted canons of construction of similar all-or-nothing statutes,

proposed use of a *de minimis* application of the Delaney Clause.

The opinion below failed to consider this unique situation, and the reasonableness of the *de minimis* interpretation as a response to it. We submit that the issues presented are of such importance that they should be considered by this Court. For these reasons, the writ of certiorari should be granted.

Respectfully submitted,

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MOTION FILED
JAN 14 1993

No. 92-800

IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Petitioner,

v.

KATHLEEN E. LES; FRANCES LES THOMAS; MANUEL JESUS PEREZ MORALES; DAVID R. PEREZ; MANUEL R. PEREZ,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

---

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF *AMICUS CURIAE* ON BEHALF OF AMERICAN SOYBEAN ASSOCIATION, NATIONAL ASSOCIATION OF WHEAT GROWERS, NATIONAL CORN GROWERS ASSOCIATION, and NATIONAL COTTON COUNCIL OF AMERICA IN SUPPORT OF PETITIONER

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MOTION FOR LEAVE TO FILE BRIEF OF AMERICAN SOYBEAN ASSOCIATION, NATIONAL ASSOCIATION OF WHEAT GROWERS, NATIONAL CORN GROWERS ASSOCIATION, and NATIONAL COTTON COUNCIL OF AMERICA IN SUPPORT OF PETITIONER

Pursuant to Rule 37.2 of the Rules of this Court, the American Soybean Association, National Association of Wheat Growers, National Corn Growers Association, and National Cotton Council of America respectfully move for leave to file the attached brief as *amici curiae* in support of the National Agricultural Chemicals Association's Petition for Writ of

Certiorari. Although counsel for Petitioner and the United States have consented to the filing of this brief, counsel for the parties which were Respondents and Respondent-Intervenors below has refused to give his consent.

The *amici curiae* are national trade associations whose members produce most of the soybeans, wheat, cotton and corn grown in the United States.[1] The *amici* estimate that the aggregate annual value of the commodities they produce is approximately $40 billion. An estimated average $11.5 billion worth of these commodities was exported annually between 1980 and 1987 alone.[2]

In order to sustain this impressive level of production, the members of the *amici* associations (referred to collectively herein as the "*amici*") depend upon access to a variety of exhaustively tested, EPA registered crop protection pesticide products to control the spread of crop destroying insects, weeds and diseases. Numerous pesticides registered for—and safely used on—soybean, wheat, corn and cotton crops would be lost under EPA's current policy if the strict read-

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[1] The **American Soybean Association** is a national commodity organization with 28,500 members, and affiliation with 29 states. The **National Corn Growers Association** represents approximately 25,000 corn farmers in 47 states. The **National Association of Wheat Growers** represents 60,000 growers in 22 states, who produce 85 percent of all U.S. wheat. The **National Cotton Council of America** is the central organization of the cotton industry, representing producers, ginners, oilseed crushers, merchants, cooperatives, warehousemen and textile manufacturers.

[2] National Research Council, *Alternative Agriculture*, at 29 (1989).

ing of the Delaney clause mandated by the Ninth Circuit is upheld.[3] Without these pesticides, the ability of the *amici* to continue to produce an affordable, abundant food supply would be jeopardized.

The *amici* seek leave to file this brief in order to describe the scope of the substantial impact of the Ninth Circuit's decision in *Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992), on American agriculture, and to illustrate the crucial role that pesticides play in the production of food and fibre. This brief will show (1) how the intent of Congress as shown in both the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y (1988 & Supp. III 1991) and the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C.A. §§301-394 (West 1972 & Supp. 1992) would be frustrated, and (2) how the integrated system for the approval and use of safe and effective pesticides by growers would be seriously compromised if the Court did not grant the National Agricultural Chemicals Association's Petition for Writ of Certiorari, and reverse the Ninth Circuit's erroneous decision.

For the foregoing reasons, *amici curiae* American Soybean Association, National Association of Wheat Growers, National Corn Growers Association, and National Cotton Council of America respectfully request that they be allowed to participate in this case by filing the attached brief.

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[3] Environmental Protection Agency, *List of Chemicals Evaluated for Carcinogenic Potential* (October 14, 1992).

Respectfully submitted,

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Dated: January 14, 1993

QUESTION PRESENTED

Does the United States Environmental Protection Agency have authority to establish a *"de minimis"* exception to § 409(c)(3)(A) of the Federal Food, Drug and Cosmetic Act (the "food additive Delaney Clause," 21 U.S.C. § 348(c)(3)(A)) to allow use of beneficial, agricultural pesticides which are carcinogenic in laboratory animals, but pose virtually no risk of cancer to consumers of processed foods?

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	iii
INTEREST OF THE AMICI	2
SUMMARY OF ARGUMENT	2
ARGUMENT	3
I. THE NINTH CIRCUIT'S DECISION WILL DEFEAT CONGRESSIONALLY MANDATED OBJECTIVES FOR THE USE OF AGRICULTURAL PESTICIDES	3
A. Frustration of Congressional Objectives Under FFDCA	5
B. Frustration of Congressional Objectives Under FIFRA	9
II. THE NINTH CIRCUIT'S STRICT READING OF THE DELANEY CLAUSE WILL PREVENT THE ADOPTION OF ENVIRONMENTALLY RESPONSIBLE FARMING TECHNIQUES	10
CONCLUSION	14

TABLE OF AUTHORITIES

CASES	Page
Chevron U.S.A., Inc. v. Hammond, 726 F.2d 483 (9th Cir. 1984), *cert. denied*, 471 U.S. 1140 (1985)	4
Les v. Reilly, 968 F.2d 985 (9th Cir. 1992)	2
Public Citizen v. Young, 831 F.2d 1108, 1113 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988)	5
Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984).	3
STATUTES	
Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C.A. §§ 301-394 (West 1972 & Supp. 1992)	3
21 U.S.C. § 346(a)(b)	4,6
21 U.S.C. § 348(c)(3)(A)	3
Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y (1988 & Supp. III 1991)	3
7 U.S.C. § 136a(b)	4
REGULATIONS	
55 Fed. Reg. 17,560 (April 25, 1990)	7,8
17,564	7,8
17,564-65	7
56 Fed. Reg. 7,750 (February 25, 1991)	4
OTHER AUTHORITIES	
S. Rep. No. 334, 95th Cong., 1st Sess. (1977)	9
S. Rep. No. 838, 92nd Cong., 2d Sess., *reprinted in 1972 U.S.C.C.A.N. 3993*	9
H.R. Rep. No. 939, 100th Cong., 2d Sess., *reprinted in* 1988 U.S. Code Cong. & Admin. News 3474, 3477	9

Table of Authorities Continued

Page

H.R. Rep. No. 1385, 83d Cong., 2d Sess. (1954), *reprinted in* 12 *A Legislative History of FFDCA and its Amendments* at 833 (Comm. Print 1979) 6

Pub. L. No. 100-532, 102 Stat. 2654 9

Before the Subcomm. on Environment, Energy, and Natural Resources of the House Comm. on Government Operations (July 23, 1992) (statement of Linda J. Fisher, Assistant Administrator for Prevention, Pesticides and Toxic Substances, EPA) 5,7,10

National Research Council, *Alternative Agriculture* (1989) 13

National Academy of Sciences, National Research Council, *Regulating Pesticides in Food: The Delaney Paradox* (1987) 7,8

Environmental Protection Agency, *List of Chemicals Evaluated for Carcinogenic Potential* (October 14, 1992) ..... Motion For Leave,3

USDA, Cooperative Extension Service, *Agricultural Statistics, National IPM Program*, Washington, D.C. (1987) 12

USDA, Agricultural Research Service, *Income Spent on Food: U.N. System of National Accounts*, National Food Review (December, 1989) 9

W.A. Allen, *The National Evaluation of Extension's Integrated Pest Management Programs* (1987) 12

Maura Dolan, *Court Bans 4 Chemicals from Processed Foods*, L.A. Times, A1, July 8, 1992 10

William Stevens, *Natural Pest Killer's Power Wanes*, New York Times, December 29, 1992 13

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BRIEF *AMICUS CURIAE* ON BEHALF OF AMERICAN SOYBEAN ASSOCIATION, NATIONAL ASSOCIATION OF WHEAT GROWERS, NATIONAL CORN GROWERS ASSOCIATION, and NATIONAL COTTON COUNCIL OF AMERICA IN SUPPORT OF PETITIONER

Petitioner and the United States Environmental Protection Agency ("EPA") having consented, the American Soybean Association, National Association of Wheat Growers, National Corn Growers Association, and National Cotton Council of America hereby

submit this brief and the accompanying Motion for Leave to File Brief as *amicus curiae*. The brief supports the position of the petitioner, the National Agricultural Chemicals Association ("NACA"), that the Ninth Circuit's decision in *Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992), raises issues of profound nation-wide significance, with "far-reaching consequences for the public, agriculture, the food and pesticide industries, and EPA's pesticide regulatory program." Petition for Writ of Certiorari at 11.

INTEREST OF THE AMICI

The interests of the *amici curiae* are set forth fully in the accompanying motion for leave to file this brief.

SUMMARY OF ARGUMENT

The amici agree with but will not repeat here the well-reasoned defense of the *de minimis* policy as it applies to pesticides, articulated previously by the EPA in its Brief to the Ninth Circuit, Petition for Rehearing, and Motion for Stay of Issuance of Mandate, and as raised in this Court through petitioner NACA's Petition for Writ of Certiorari. Rather, this brief will demonstrate the nationwide significance of the Ninth Circuit's decision by describing the effects of that decision on agriculture.

Specifically, this brief will show how the unwarranted loss of valuable pesticide products and uses due to the Ninth Circuit's extraordinarily rigid interpretation of the Delaney clause will (1) frustrate the congressionally mandated objectives of providing farmers with access to the effective and affordable products they need on the farm, and of assuring a safe, affordable and abundant food supply, and (2)

prevent the full implementation and adoption of modern farming practices which are more sensitive to the environment.

ARGUMENT

I. THE NINTH CIRCUIT'S DECISION WILL DEFEAT CONGRESSIONALLY MANDATED OBJECTIVES FOR THE USE OF AGRICULTURAL PESTICIDES

The use of agricultural pesticides in the United States is regulated under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y (1988 & Supp. III 1991), which this Court has described as a "comprehensive regulatory statute," *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). FIFRA's regulation of pesticide use is integrated with another federal law directed to regulating the consequences of such use in connection with food and food products. The Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C.A. §§301-394 (West 1972 & Supp. 1992), requires EPA to establish allowable residue levels in crops and certain processed foods (i.e., tolerances) for pesticide products which are registered for use under FIFRA.[4] As both the express terms and legislative histories of FIFRA and FFDCA show, Congress has recognized the valuable role played by pesticides in agricultural production and the need for a balanced regulatory approach to their safe and beneficial use.

At issue in this case is the proper interpretation of the Delaney clause (FFDCA § 409(c)(3)(A), 21 U.S.C. § 348(c)(3)(A)), considering the otherwise con-

[4] FFDCA § 408 directs EPA to establish tolerances for pesticide residues in raw agricultural commodities, and § 409 directs EPA to establish tolerances for pesticide residues in processed foods.

sistent treatment of pesticides under FIFRA and other FFDCA provisions. A rigid interpretation of that clause results in two separate conflicts, which EPA must reconcile. First, a pesticide is registered for use under FIFRA if it does not pose "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136a(b). The pesticide-specific tolerance provision of the FFDCA (§ 408, known as the "pesticide residue provision") also utilizes a similar risk-benefit balancing scheme. 21 U.S.C. § 346a(b). The solitary exception to this unified standard is the Delaney clause (§ 409 of the "food additive provision") which, if read literally, would establish a zero-risk standard. Consequently, the risk-benefit FIFRA standard is in direct conflict with the risk-only Delaney clause of the FFDCA.

A second conflict is within the FFDCA itself: between § 408 (the pesticide residue provision, which allows a risk-benefit consideration in establishing a tolerance), and § 409 (the food additive provision, which contains the zero-risk Delaney clause). In order to logically reconcile and make regulatory sense of these conflicting provisions, EPA adopted a *de minimis* interpretation to the Delaney clause. 56 Fed. Reg. 7750 (Feb. 25, 1991). By vacating EPA's *de minimis* interpretation, the Ninth Circuit has improperly second-guessed EPA's resolution of these conflicts,[5] and frustrated congressional intent with regard to the availability and use of pesticides.

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[5] *See, Chevron U.S.A., Inc. v. Hammond*, 726 F.2d 483 (9th Cir. 1984), *cert. denied*, 471 U.S. 1140 (1985). This is particularly

The impact of the Ninth Circuit's ruling on the *de minimis* interpretation is not merely academic—valuable pesticide products and uses will be lost.[6] As set forth below, the legislative histories of both FIFRA and FFDCA repeatedly confirm the valuable and necessary role played by pesticides in agricultural production. EPA's *de minimis* interpretation is an appropriate vehicle to implement Congress' legislative design, and should be upheld, because it furthers rather than frustrates Congress' primary goals. *Public Citizen v. Young*, 831 F.2d 1108, 1113 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988).

A. Frustration of Congressional Objectives Under the Federal Food, Drug and Cosmetic Act

Congress has repeatedly acknowledged the unique role of pesticides in the FFDCA. As early as 1954, when that statute was amended to explicitly address pesticide residues, Congress found that:

> These chemicals have become vital tools in the production of an *adequate, wholesome and economical food supply*, and it is accepted that without them the health and living standards of this Nation and of other coun-

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true here, as the complex scheme for the regulation of pesticides involves " 'reconciling conflicting policies' 'committed to the agency's care by the statute.' " *Id.*, 467 U.S. at 844.

[6] Shortly after the Ninth Circuit's ruling, EPA's Assistant Administrator for Prevention, Pesticides and Toxic Substances stated that EPA had identified "roughly 30 pesticides" which would be effected. However, that number could grow as food processing data or new studies "show that additional chemicals or crops are within the scope of the Delaney clause." 19 *Before the Subcomm. on Environment, Energy, and Natural Resources of the House Comm. on Government Operations* (July 23, 1992).

> tries dependent upon our food exports would be dangerously impaired.

H.R. Rep. No. 1385, 83d Cong., 2d Sess. 4 (1954), *reprinted in* 12 *A Legislative History of the FFDCA and its Amendments* at 833, 836 (Comm. Print 1979) (*Leg. Hist.*) (emphasis added). This understanding of the role and benefits of pesticides was expressly relied upon when the balancing standard used in the pesticide residue provision was developed. *Id.* at 8; 12 *Leg. Hist* at 840. This standard is integral to FIFRA's and FFDCA's overall regulatory scheme, of which the Delaney clause is a small but important part.

The same benefits which Congress recognized in 1954 remain as an important part in the current FFDCA. Today, when the Administrator issues a regulation to establish acceptable levels of pesticide residue on a raw agricultural commodity under FFDCA § 408, the Administrator is required to give appropriate consideration, among other factors, to " . . . the necessity for the production of an *adequate, wholesome,* and *economical* food supply." 21 U.S.C. § 346a(b) (emphasis added). An unfortunate but certain result of the Ninth Circuit's decision will be to remove many of agriculture's "vital tools," and make the production of an adequate, wholesome and economical food supply vastly more difficult.

Pesticides greatly assist amici's members in producing an *adequate* year-round food supply. Prior to the development of pesticides, when a serious disease or pest infestation would occur, the farmer would generally lose much of the entire crop. Even today, at least until needed pest and disease resistant varieties are developed, farmers *must* have a ready ac-

cess to appropriate, EPA-regulated pesticides to ensure that the food supply remains "adequate."

The Ninth Circuit's refusal to recognize EPA's *de minimis* interpretation ignores the legislative history of the FFDCA, and will most certainly have a significant adverse effect on the production of an adequate food supply. This result was suggested by the National Academy of Sciences and repeated by EPA earlier in the administrative record leading to this action,[7] when EPA concluded that a strict application of the Delaney clause could substantially increase the price and decrease the availability of certain foods, especially fruits and vegetables. 55 Fed. Reg. 17,560, 17,564-65 (April 25, 1990).

Pesticides are also an important factor in agriculture's mission to produce a *wholesome* food supply. After release of the decision in *Les v. Reilly* last summer, EPA's Assistant Administrator for Pesticides, Prevention and Toxic Substances concluded that the decision did not advance the congressional objective of a wholesome food supply. She said:

> . . .if the Ninth Circuit's decision stands at the end of the day, I foresee far-reaching and dramatic impacts on pesticide use in this country. *While I wish that I could say that these changes will contribute measurably to the safety of the food supply, it is not at all clear that that would be true.*

Before the Subcomm. on Environment, Energy, and Natural Resources of the House Comm. on Government

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[7] National Academy of Sciences, *Regulating Pesticides in Food: The Delaney Paradox* at 41-42, (1987). EPA adopted this conclusion at 55 Fed. Reg. 17,564 (April 25, 1990).

Operations 22 (July 23, 1992) (statement of Linda J. Fisher, EPA) (emphasis added). Indeed, the National Academy of Science concluded in 1987 that this very scenario may actually have adverse effects on food safety.[8] EPA agreed, and concluded that precisely the same reading of the Delaney clause which the Ninth Circuit now demands may actually create *increased* health risks due to increased production of natural toxins in plants, and may even lead to use of pesticides which pose relatively *higher* risk. 55 Fed. Reg. 17,560, 17,564.

Finally, pesticides greatly assist producers in providing Americans with an *affordable* food supply. 55 Fed. Reg. 17,560, 17,564. Americans currently spend a smaller percentage of their disposable income on food than do most other countries in the world.[9] To

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[8] According to the NAS:

> The committee can envision situations in which the current system would compel results that, at least in the short term, actually increase the human cancer risks from pesticides. For example, suppose a registered pesticide X with known oncogenic effects and an existing substitute Y which is a weaker oncogen are under review. Both agents produce roughly equal benefits for comparable uses. X does not concentrate in any processed apple products, but Y concentrates marginally. The EPA could be forced by the Delaney Clause to deny a section 409 tolerance for Y and also would be compelled to cancel its 408 tolerance and registration. Pesticide X would claim a larger share of the market. Human cancer risk would rise, not fall. National Academy of Sciences, National Research Council, *Regulating Pesticides in Food: The Delaney Paradox* at 41-42 (1987).

[9] Americans spend 10% of their disposable income on food,

maintain such low cost, today's farmers must choose wisely from among available pesticides. Because the cost of food and fibre is directly linked to the cost of inputs, farmers must select not only the most effective, but also the most economical pesticides available. The loss of many important pesticides through misinterpretation of the Delaney clause will significantly affect growers' costs and increase the cost of food and fibre.

B. Frustration of Congressional Objectives Under the Federal Insecticide, Fungicide and Rodenticide Act

When Congress undertook a comprehensive revision to FIFRA in 1972, it succinctly summarized the role of pesticides in modern American agriculture by stating that "[p]esticides are essential to man's food supply both as to quality and quantity." S. Rep. No. 838, 92nd Cong., 2d Sess. 3, *reprinted in* 1972 U.S. Code Cong. & Admin. News 3993, 3995. Five years later Congress reaffirmed that an "overriding concern of FIFRA is that pesticides should be available to meet pest control needs." S. Rep. No. 334, 95th Cong., 1st Sess. 3, 5 (1977). And yet again, during the amendments to FIFRA which launched the current reregistration program[10], Congress confirmed that the purpose of the amendments was, in part, "to ensure that . . . agricultural producers, will have access to the effective and affordable products they need on the farm." H.R. Rep. No. 939, 100th Cong., 2d Sess.

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compared with the European Community (14%), Russia (28%), China (48%), and India (53%). USDA, Agricultural Economic Research Service, *Income Spent on Food: U.N. System of National Accounts*, National Food Review, December 1989.

[10] *See*, Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988, Pub. L. No. 100-532, 102 Stat. 2654.

28, *reprinted in* 1988 U.S. Code Cong. & Admin. News 3474, 3477.

The use of EPA-regulated pesticides is a congressionally sanctioned, integral part of the current efficient, low cost system of food and fibre production. Yet, the Ninth Circuit's decision could very likely result in the eventual *loss* of at least thirty (30) essential pesticides[11]. Even if EPA were to adopt procedures or definitions to cushion the blow, should the Ninth Circuit's decision eventually be upheld, farmers will be left with significantly fewer pesticides to combat increasing numbers of weeds, pests and diseases. Consequently, the congressional objective of providing *amici* with access to those products which they need in the production of their crops will be defeated if EPA is required to begin revoking tolerances which exceed the zero-risk Delaney clause standard.

II. THE NINTH CIRCUIT'S STRICT READING OF THE DELANEY CLAUSE WILL PREVENT ADOPTION OF ENVIRONMENTALLY RESPONSIBLE FARMING TECHNIQUES

The loss of an array of available chemical pest control products will not merely disrupt the production and availability of food. Because the FFDCA is con-

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[11] EPA's Assistant Administrator for Prevention, Pesticides and Toxic Substances has testified that "roughly 30" pesticides would be affected, but cautioned that the number represented "only a portion of the total universe that *could* be affected." *Before the Subcomm. on Environment, Energy, and Natural Resources of the House Comm. on Government Operations* 22 (July 23, 1992) (emphasis added). Respondents' lead counsel has asserted that "[d]ozens" of pesticides "could be banned." Maura Dolan, *Court Bans 4 Chemicals from Processed Foods*, L.A. Times, July 8, 1992, at A1.

cerned with the safety of food, the environmental impact of a strict interpretation of the Delaney clause is not readily apparent. However, the loss of a pesticide due to the Delaney clause may well result in the use of alternative pest control methods or devices which are less environmentally desirable. For example, if an important herbicide is no longer available, the result may be greater environmental damage due to increased need for plowing and tilling, or the reversion of farmland to noxious weeds.

Additionally, many of the incentives for growers to adopt or implement environmentally desirable farming techniques will also be lost. In order to effectively and economically control pests, farmers need both chemical and non-chemical pest control strategies. One such strategy is known as Integrated Pest Management ("IPM"). IPM encourages farmers to practice a combination of environmentally sensitive farming practices. It is generally defined as a pest and plant disease control strategy which is based on the determination of an economic threshold that indicates when a pest population or disease is approaching the level at which control measures are necessary to prevent a decline in net returns—that is, when the predicted value of the impending crop damage exceeds the cost of controlling the pest. The key to IPM is the exercise of prudence in the use of external—including pesticidal—inputs. However, strategies such as IPM are dependent on the continued *availability* of a *variety* of traditional chemical solutions when alternative strategies fail.

There are three general components of IPM: cultural practices (appropriate crop/soil selection, crop rotation, tillage practices, and careful timing for

watering and weeding), monitoring pests and diseases (generally by careful scouting), and treatment (with a pesticide) if the pest or disease reaches a pre-determined level of economic damage. Before a farmer would adopt an IPM strategy, he or she must be sure that a variety of products needed for treatment will be available if the cultural practices fail.

IPM has been practiced in varying degrees since the late 1960's but it is now rapidly gaining acceptance among farmers. By 1986, nearly 40 million acres of soybean, wheat, corn and cotton cropland alone were successfully grown utilizing IPM techniques to control pests and plant diseases. Those already impressive numbers are expected to increase significantly through the 1990's and beyond. USDA, Cooperative Extension Service, *Agricultural Statistics, National IPM Program*, Washington, D.C. (1987). However, the effectiveness of IPM continues to "rely on precise application of specific pesticides." W.A. Allen, *The National Evaluation of Extension's Integrated Pest Management Programs*, Virginia Cooperative Extension Service, 1987. A decrease in available pesticide products due to a strict reading of the Delaney clause will lead directly to a loss of acres utilizing IPM techniques.

Finally, the availability of fewer pesticidal products will further exacerbate another environmental problem: pest resistance. In a 1987 report, the National Research Council addressed pest resistance, a condition which results from repeated exposure to the same product, and concluded that:

> *Long-term adverse implications can also arise from recurrent use of the same or related*

> *pesticides.* The emergence of pesticide resistant pest populations is a particularly worrisome phenomenon. Neglecting pest resistance may lead to higher volume or more frequent application of pesticides, with serious economic consequences for the individual farmer, the industry, and even the nation.

National Research Council, *Alternative Agriculture* 10 (1987) (emphasis added). As the number of available pesticide products diminishes due to the Ninth Circuit's decision, farmers will become more dependent on fewer products when the need to control a pest infestation arises,[12] and may unwittingly contribute to an increase in pest resistance.

EPA's use of a *de minimis* interpretation allows the agency to reconcile conflicting statutory provisions, while simultaneously assuring farmers that a variety of pest control products would be available to meet their needs. All of this was accomplished while assuring the public that products whose risks outweighed their benefits would not be used. The Ninth Circuit's failure to recognize the value and wisdom of that interpretation will hurt not only agriculture, but may threaten the nation's food supply and environment as well.

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[12] The problem of pest resistance is not unique to chemical pesticides. A recent New York Times article described how this phenomena is already decreasing the effectiveness of new biological pesticides. The article quotes Dr. R. James Cook, of the Washington State University Department of Agriculture as cautioning "It's really important never to put all your eggs in one basket and to use a diversity of approaches." William Stevens, *Natural Pest-Killer's Power Wanes,* New York Times, December 29, 1992, at C1.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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Dated: January 14, 1993

MOTION FILED
JAN 14 1993

No. 92-800

IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Petitioner,

v.

KATHLEEN E. LES, *ET AL.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF THE GROCERY MANUFACTURERS OF AMERICA, INC., THE NATIONAL FOOD PROCESSORS ASSOCIATION, AND TEN OTHER FOOD INDUSTRY TRADE ASSOCIATIONS* AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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AMERICAN BAKERS ASSOCIATION

AMERICAN FROZEN FOOD INSTITUTE

AMERICAN SPICE TRADE ASSOCIATION

CHOCOLATE MANUFACTURERS ASSOCIATION

INTERNATIONAL DAIRY FOODS ASSOCIATION

NATIONAL CONFECTIONERS ASSOCIATION

NATIONAL COUNCIL OF FARMER COOPERATIVES

PRODUCE MARKETING ASSOCIATION

SNACK FOOD ASSOCIATION

UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION

MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

Movants are food industry trade associations having a substantial interest in the outcome of this case. The member companies of these associations together produce the bulk of consumer food products subject to the food additive provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 348) including the Delaney Clause (21 U.S.C. 348(c)(3)(A)), and they therefore have a vital interest in urging that the decision of the court of appeals interpreting that provision be reviewed by this Court. By this motion, they request leave to file the accompanying brief as *amici curiae* in support of petitioner.

Movant Grocery Manufacturers of America, Inc. (GMA) submitted an *amicus* brief in the court of appeals with the consent of all parties. Movants National Food Processors Association (NFPA) and United Fresh Fruit and Vegetable Association have petitioned the Environmental Protection Agency (EPA) in the matter cited in footnote six of the Federal respondents' brief in opposition. The government's reference to that petition recognizes the important interest of the food industry in this case.

Petitioner and the Federal respondent have consented to the filing of the accompanying brief in this Court, and their consents are on file with the Clerk. Counsel for the non-Federal respondents has refused to consent, necessitating the submission of this motion pursuant to Rule 37 of the Rules of this Court.

GMA is a national trade association of more than 130 companies that manufacture and distribute products primarily sold in retail grocery stores throughout the United States. GMA's member companies employ more than 2.5 million people and have annual sales of more than $250 billion.

NFPA is the science-based association of the food industry, whose 500 members manufacture the nation's

processed packaged fruits and vegetables, juices and drinks, meat and poultry, seafood, and specialty products.

The American Bakers Association (ABA) is the national trade association representing the wholesale baking industry. The membership of the ABA consists of 200 baker members and 174 allied members who together manufacture approximately 85 percent of the baked goods sold in the United States.

The American Frozen Food Institute (AFFI) is a national trade association representing frozen food processors and companies that supply goods and services to the frozen food processing industry. AFFI's 550 corporate members produce over 90 percent of the total U.S. production of frozen food.

The American Spice Trade Association (ASTA) was founded in 1907 by the people who brought spices to the United States. The membership currently includes growers, overseas shippers, agents, brokers, importers, processors and dehydrators in this country, as well as many firms associated and allied with the industry. ASTA represents more than 300 member firms worldwide and is active in research, trade relations within and outside the industry, and spice education.

The Chocolate Manufacturers Association and the National Confectioners Association together represent the 97 companies who are responsible for the substantial majority of the sales of confectionery products in the United States. The confectionery industry is a significant user of agricultural commodities, being the second largest user of sugar, after baked products, and the third largest user of peanuts, after peanut butter and salted nuts, and a user of about four billion pounds of milk and milk products annually.

The International Dairy Foods Association (IDFA) is a national trade association representing three affiliated organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute.

These organizations together represent approximately 700 member companies which account for 85 percent of the processors and manufacturers of dairy foods in the United States.

The National Council of Farmer Cooperatives is a nationwide association of cooperative businesses which are owned and controlled by farmers. Its membership includes over 100 agricultural marketing, supply and credit cooperatives, plus 32 state councils. National Council members handle practically every type of agricultural commodity produced in the United States, market these commodities domestically and around the world, and furnish production supplies and credit to their farmer members and patrons. The National Council represents about 90 percent of the nearly 5,000 local farmer cooperatives in the nation, with a combined membership of nearly 2 million farmers.

The Produce Marketing Association (PMA) is the largest national trade association representing companies that market fresh fruits, vegetables, and floral products. PMA's membership of 2,650 includes growers, supermarket retailers, food service operators, and importers. Domestically, PMA members handle more than 90 percent of fresh produce sold.

The Snack Food Association is the trade association representing more than 500 domestic manufacturers and suppliers involved in the production and distribution of snack food products made from vegetables, grains, fruits, meats, and nuts consumed in the United States. While there are nationwide companies in the association, many are moderately sized regional businesses.

The United Fresh Fruit and Vegetable Association is the national trade organization which represents all sectors of the fresh produce industry. Founded in 1904, its 2,100 member firms are grower/shippers, brokers, truckers and other transportation specialists, wholesalers, foodservice distributors

and operators, retailers, allied suppliers and related educational and scientific organizations in the United States and abroad.

* * * *

The decision of the court of appeals that petitioner National Agricultural Chemicals Association asks this Court to review, if allowed to stand, would produce grave and far-reaching consequences for the cost and availability of the food supply and the nutritional health of consumers without any compensating public benefit. The decision would ban numerous invaluable pesticides which the EPA finds present only a *de minimis* risk to health while undermining the agricultural production, quality, and availability of fruit, vegetable, and grain products which public health officials have determined are essential for good health.

The food industry trade associations on many other occasions and in other cases have acted vigorously to protect the rights of their member companies and food consumers and to express their views on important issues relating to the regulation of the food supply. GMA did so in this case through the brief it filed as *amicus curiae* in the Ninth Circuit. The food industry associations believe that the attached brief can make an important contribution to the Court's decision whether to grant the petition for a writ of certiorari in this case. The brief supplements and is not redundant with the arguments presented in the petition for a writ for certiorari and documents the serious adverse consequences of the court of appeals' decision with respect to the food supply. As the attached brief shows, the court of appeals overstepped its authority by rejecting EPA's reasonable interpretation of the FFDCA in contravention of the now well settled doctrines of statutory interpretation established by this Court, and its decision should be overturned.

Accordingly, the food industry trade associations move for leave to file the attached brief *amici curiae*.

Respectfully submitted,

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QUESTION PRESENTED

Whether the Environmental Protection Agency reasonably construed the food additive Delaney Clause, 21 U.S.C. 348(c)(3)(A), to permit the continued use of substances that present only a *de minimis* risk of cancer.

TABLE OF CONTENTS

Page

INTEREST OF THE *AMICI CURIAE* 1

STATEMENT OF THE CASE 1

SUMMARY OF ARGUMENT 3

ARGUMENT 4

I. THE DECISION OF THE COURT OF APPEALS JEOPARDIZES THE NATION'S FOOD SUPPLY 4

II. EPA'S *DE MINIMIS* INTERPRETATION OF THE STATUTE IS AUTHORIZED AND REASONABLE 7

A. Agencies Have Inherent Authority To Exclude *De Minimis* Matters From Regulation 8

B. The Legislative History Supports The *De Minimis* Policy 9

C. The Court of Appeals Ignored the *Chevron* Doctrine That Courts Should Defer To Reasonable Agency Interpretations of Inconsistent or Ambiguous Statutory Provisions 11

III. THE *DE MINIMIS* POLICY IS CONSISTENT WITH ADMINISTRATIVE PRACTICE 17

TABLE OF CONTENTS — Continued

IV. THE SOLICITOR GENERAL'S OPPOSITION TO REVIEW IN THIS CASE IS INCONSISTENT WITH HIS POSITION IN AN EARLIER COLOR ADDITIVE CASE . . 19

CONCLUSION 20

TABLE OF AUTHORITIES

CASES

Alabama Power Co. v. *Costle*, 636 F.2d 323 (D.C. Cir. 1979) 9

Chevron U.S.A., Inc. v. *NRDC*, 467 U.S. 837 (1984) . . . . . *passim*

Cosmetic, Toiletry and Fragrance Association v. *Public Citizen*, No. 87-1194 19

Flemming v. *Florida Citrus Exchange*, 358 U.S. 153 (1958) 8

Industrial Union Department, AFL-CIO v. *American Petroleum Institute*, 448 U.S. 607 (1980) 8

Les v. *Reilly*, 968 F.2d 985 (9th Cir. 1992) . . . . . *passim*

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Permian Basin Area Rate Cases, 390 U.S. 747 (1968) . . . 8

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Scott v. *FDA*, 728 F.2d 322 (6th Cir. 1984) 19

United States v. *1,500 Cases More or Less, Tomato Paste*, 236 F.2d 208 (7th Cir. 1956) 9

United States v. *Ewig Brothers Co.*, 502 F.2d 715 (7th Cir. 1974) 15

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TABLE OF AUTHORITIES — Continued

Wisconsin Department of Revenue v. *William Wrigley, Jr., Co.*, 112 S. Ct. 2447 (1992) 8

Young v. *Community Nutrition Institute*, 476 U.S. 974 (1986) 17

STATUTES AND REGULATIONS

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. et seq.
§ 201(s); 21 U.S.C. § 321(s) 14
§ 201(s)(2); 21 U.S.C. § 321(s)(2) 15,16
§ 402(a)(1); 21 U.S.C. § 342(a)(1) 8
§ 402(a)(2)(C); 21 U.S.C. § 342(a)(2)(C) . . . . *passim*
§ 408; 21 U.S.C. § 346a . . . . . *passim*
§ 409; 21 U.S.C. § 348 . . . . . *passim*
§ 409(c)(3)(A); 21 U.S.C. § 348(c)(3)(A) 2

Federal Fungicide, Insecticide, and Rodenticide Act
§ 4; 7 U.S.C. § 4 5

21 C.F.R. 170.3(e) (1992) 6

15 Fed. Reg. 321 (January 19, 1950) 18

19 Fed. Reg. 1239 (March 5, 1954) 18

32 Fed. Reg. 5675 (April 6, 1967) 18

34 Fed. Reg. 19073 (December 1, 1968) 18

44 Fed. Reg. 59509 (October 16, 1979) 6

48 Fed. Reg. 50528 (November 2, 1983) 19

54 Fed. Reg. 27700 (June 30, 1989) 1

55 Fed. Reg. 17560 (April 25, 1990) 1

55 Fed. Reg. 26498 (June 28, 1990) 1

TABLE OF AUTHORITIES — Continued

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57 Fed. Reg. 17389 (April 27, 1992) 5

58 Fed. Reg. 2537 (January 6, 1992) 5

LEGISLATIVE MATERIALS

Food Additives: Hearings Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce, 85th Cong., 1st & 2d Sess. 38-39 (1957 & 1958) 10

Statement of Linda Fisher, Assistant Administrator for Pesticides and Toxic Substances of the Environmental Protection Agency before the Subcomm. on Environment Energy, and Natural Resources of the House Comm. on Government Operations (July 23, 1992) (unpublished) 4

H.R. 13254, 85th Cong., 2d Sess. (July 1, 1958) 15

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S. Rep. No. 2422, 85th Cong., 2d Sess. 6 (1958) 9,10

104 Cong. Rec. 17414 (1958) 10

104 Cong. Rec. 17415 (1958) 15

106 Cong. Rec. 15380 (1960) 11

MISCELLANEOUS

Brady, *Responsibility, Freedom and the Law*, 17 Food Drug Cosm. L.J. 323 (1962) 11

National Research Council, *Regulating Pesticides in Food: The Delaney Paradox* (1987) 13

TABLE OF AUTHORITIES — Continued

P. Hutt & R. Merrill, *Food and Drug Law*, chapter 8 (2d ed. 1991) 18

Speech by William K. Reilly before the National Agricultural Chemicals Ass'n Annual Meeting (September 28, 1992) 6

INTEREST OF THE *AMICI CURIAE*

As shown in the foregoing motion, *amici* are national food trade associations having a substantial interest in the outcome of this case.

STATEMENT OF THE CASE

Respondents Kathleen E. Les *et al.* sought direct review in the United States Court of Appeals for the Ninth Circuit of a final order of the Environmental Protection Agency (EPA) refusing to revoke approvals for certain pesticides. Petitioner National Agricultural Chemicals Association intervened in the court of appeals in support of the EPA's order. The court of appeals set aside the order, and this petition followed.

1. Respondents filed a petition with EPA on May 25, 1989, requesting that EPA revoke eleven food additive regulations covering seven pesticides. *See* 54 Fed. Reg. 27700 (June 30, 1989). EPA initially granted the petition in part and denied it in part, determining in particular that it would not revoke the approvals for pesticides presenting a negligible or *de minimis* risk of cancer to humans. *See* 55 Fed. Reg. 17560 (April 25, 1990). Respondents objected to EPA's decision on May 22, 1990. *See* 55 Fed. Reg. 26498 (June 28, 1990). EPA adhered to its *de minimis* policy in responding to the objections on February 25, 1991. *See* Pet. App. 12a.

In its final decision, EPA emphasized the trivial nature of the risks presented by the pesticides to which the *de minimis* policy applied. *See id.* at 32a - 45a. These risks are not actuarial risks based on past experience. There is, in fact, no evidence whatever that anyone has ever contracted cancer from ingesting food treated with any of the pesticides in question. Rather, the risks computed by EPA are upper-bound estimates extrapolated from animal studies to potential human exposures using highly conservative "worst case" assumptions. The agency explained that a risk estimate such as one in one million "does not represent the actual risk" and that the true risk "may, in fact, be lower, even as low as zero." *Id.* at 33a. At most,

such a risk might increase the expected number of cancer cases in a population of one million U.S. residents from 250,000 to 250,001 (an increase of 4/10,000 of one percent). By comparison, similar computed risks are associated with eating one peanut with the maximum permitted level of aflatoxin every 250 days or spending 17 hours per year in miles high Denver, with its greater exposure to radiation. *Id.* at 33a - 34a.

With these facts in mind, EPA reasoned that Congress did not intend an extraordinarily rigid interpretation of the food additive Delaney Clause (21 U.S.C. 348(c)(3)(A)) that would bar approval of pesticides associated with such insignificant risks. The agency reviewed at length "the larger statutory framework involving the regulation of pesticides," and concluded that "interpreting the Delaney Clause as containing a *de minimis* exception helps reduce the conflict in the [Federal Food, Drug, and Cosmetic Act (FFDCA)] and between the FFDCA and [the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)]." *Id.* at 100a. Relying on the statute and well-settled principles of administrative authority, EPA exercised its inherent discretion under the *de minimis* doctrine, and concluded that the law permits continued approval of these pesticides. The contrary result, EPA found, would be unreasonable because it would require that pesticide approvals be revoked on the basis of an essentially nonexistent human risk. *See id.* at 45a - 108a.

2. The court of appeals set aside the order. *Id.* at 1a - 11a. Respondents did not challenge EPA's factual findings, and the court of appeals did not disturb them. Nonetheless, the court held that the Delaney Clause allows EPA "no discretion." *Id.* at 6a - 7a. The court rejected the EPA's contention that a *de minimis* exception to the Delaney Clause is necessary to reconcile the conflicting statutory policies and provisions applicable to pesticides. The court reached this result in large part based on its belief that the Delaney Clause has been

uniformly "interpreted as an absolute bar to all carcinogenic food additives". *Id.* at 9a.

SUMMARY OF ARGUMENT

This Court should grant the petition for a writ of certiorari because the court of appeals erred in failing to defer to EPA's reasonable interpretation of section 409 of the FFDCA, including the Delaney Clause, and that error will have substantial disruptive consequences for the Nation's food supply.

Advances in testing and analytical technologies have made it increasingly clear that virtually the entire food supply contains substances that have been shown in animal feeding studies to be carcinogenic. EPA has identified a large number of valuable pesticides that are animal carcinogens but pose at most a negligible risk to humans. The loss of these pesticides would jeopardize the food supply and threaten consumer health, without providing any compensating public benefit. In addition, many common food substances are animal carcinogens and could be considered food additives subject to the Delaney Clause and therefore banned under the ruling of the court of appeals.

The decision below is manifestly incorrect. EPA acted well within its statutory authority and in a manner entirely consistent with both the legislative history and regulatory precedents. The court of appeals overstepped its authority by relying on blind literalism as an excuse for requiring a rigid and insupportable "zero risk" rule that was never intended by Congress and would wreak havoc with the food supply.

The court of appeals' construction of the statute ignores the doctrine that agencies have inherent authority to address *de minimis* risks in a sensible manner, and that therefore this authority need not be stated expressly in the law. The court also failed even to cite *Chevron U.S.A., Inc.* v. *NRDC*, 467 U.S. 837 (1984), under which it was required to defer to the EPA's reasonable interpretation of the statute. Given the

complexity and internal contradictions of the statutory scheme at issue here, there could be no stronger case in which to heed the wisdom of *Chevron*.

Finally, the Solicitor General urged the Court to deny review in an earlier case involving the color additive Delaney Clause, in favor of review in a food additive case. Such a case is now before the Court, and the reasons given by the Solicitor General in his earlier filing further counsel in favor of review here.

ARGUMENT

I. THE DECISION OF THE COURT OF APPEALS JEOPARDIZES THE NATION'S FOOD SUPPLY.

This case presents an issue of overriding importance to consumers and food producers: whether a substance must be banned merely because it may be carcinogenic in laboratory rats or mice, when any risk to humans is essentially nonexistent. This question is important because virtually every food contains substances meeting this description. The continued lawfulness of these foods is jeopardized by the decision below.

The court of appeals' decision, if allowed to stand, would have a far-reaching detrimental impact on EPA's pesticide regulatory program, the United States' food producers, and consumers. EPA's present policy would compel it to prohibit the use of large numbers of valuable pesticides that have been found to pose trivial risks, and the Agency would be forced to divert limited resources from pesticide regulatory activities of far greater public importance.

Although the court of appeals' decision directly involved tolerances for only four pesticides, EPA has acknowledged that at least thirty, and probably well over sixty, food use pesticides may be required to be banned under the Court's holding. Linda Fisher, EPA Assistant Administrator for Pesticides and Toxic Substances, testified before Congress in July that the loss of these pesticides is likely to have profound adverse consequences

without any measurable contribution to food safety. Statement Before the Subcommittee on Environment, Energy, and Natural Resources of the House Committee on Government Operations (July 23, 1992).

The prohibition of numerous valuable food-use pesticides, as required by the Ninth Circuit decision, would disrupt agricultural production, diminish food quality, increase costs to consumers and reduce the availability and consumption of nutritious fruit, vegetable, and grain products. This would not only cause serious economic harm to food producers and consumers, but would jeopardize consumer health by inhibiting the consumption of the very food products which public health authorities have urged the public to consume in greater quantities. *See, e.g.*, 58 Fed. Reg. 2537-51 (January 6, 1993) (promulgating final FDA rule authorizing health claims for fruits and vegetables relating diets high in these foods to a reduced risk of cancer).

The adverse impact on EPA's pesticide program would be equally dramatic. EPA would be required to undertake lengthy and burdensome administrative proceedings in connection with pesticides required to be banned under the zero risk standard imposed by the Ninth Circuit. This would divert scarce EPA resources from completion of the pesticide reregistration program. Section 4 of FIFRA (7 U.S.C. § 4) requires a complete reexamination, to be completed by 1997, of the human health and environmental effects of all pesticides registered prior to 1988. By triggering scores of tolerance revocation proceedings with respect to pesticides posing *de minimis* risks, the Ninth Circuit decision would hamper the reregistration program and delay the cancellation of truly hazardous pesticides. It would also reduce the resources available for EPA to carry through pesticide regulatory proposals that address numerous other critical safety issues. 57 Fed. Reg. 17389 (April 27, 1992).

Finally, the risk to the public would be increased by forcing EPA to ban beneficial pesticides that pose *de minimis* cancer risks and requiring the substitution of pesticides posing greater health risks which are not associated with cancer. *See* Speech by William K. Reilly before the National Agricultural Chemicals Ass'n Annual Meeting 4 (Sept. 28, 1992).

While the facts before the court of appeals involved pesticides, the same statutory Delaney Clause applies generally to all food additives. Many food additives, such as preservatives, provide important health protection to the American public. In general, food additives of many kinds are essential to the production of a safe, varied, and plentiful food supply. Like certain pesticides, however, some of these food additives have been associated with cancer in animal studies. The court of appeals' decision, if allowed to stand, would call into question the continued approval of these substances.

In fact, trace amounts of animal carcinogens are present in virtually all foods, as FDA has recognized. *See*, *e.g.*, 44 Fed. Reg. 59509, 59513 (October 16, 1979). Advances in testing methodologies have led to the identification of an ever-increasing universe of substances that are animal carcinogens. At the same time, advances in analytical technologies have allowed scientists to identify these trace constituents at ever-lower levels in foods, often measured in parts per billion. The inevitable result of these twin developments has been a showing that the entire food supply contains animal carcinogens at very low levels. These include essential nutrients, such as vitamins and protein; raw agricultural commodities, such as egg yolk; and substances added through food processing, such as salt and water (which contains a number of animal carcinogens). Under the comprehensive FFDCA definition of "food additive," virtually all of these substances could be considered food additives subject to the Delaney Clause. *See* 21 C.F.R. 170.3(e).

Notwithstanding their safety in humans, these substances could be considered unlawful food additives under the decision of the court of appeals. It would cause substantial economic disruption, interfere with the production and availability of a wholesome, varied, and affordable food supply, and adversely affect the public health to interpret the Delaney Clause to require the banning of food additives that present only a *de minimis* risk of cancer.

II. EPA'S *DE MINIMIS* INTERPRETATION OF THE STATUTE IS AUTHORIZED AND REASONABLE.

The court of appeals fundamentally misunderstood the Delaney Clause. That provision was never intended by Congress, and has never been interpreted by the relevant agencies, as the sweeping, absolute barrier that the court below thought it was. There are numerous statutory and administrative exceptions to the Delaney Clause, which belie any notion that the statute is a rigid bar to the use of any animal carcinogen, regardless of the degree of human risk.[1] When both the Delaney Clause and the nature of the agency's authority are fully understood, it will be seen that the *de minimis* policy is amply supported.

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[1] For example, the Delaney Clause does not apply to substances shown to cause cancer in animals through models that are not appropriate or relevant to an evaluation of human safety; secondary carcinogens (substances that cause a physiologic change that causes cancer); carcinogenic contaminants in food within established limits; carcinogenic constituents of food additives and color additives if they pose a *de minimis* risk; carcinogenic animal drugs if their detectable residues pose a *de minimis* risk; carcinogenic substances that are not considered food additives because they are present in amounts that pose a *de minimis* risk; and carcinogens that are ubiquitous in the environment and present in food additives or color additives in amounts that pose a *de minimis* additional risk. *See* pages 18-19 *infra*.

A. Agencies Have Inherent Authority To Exclude *De Minimis* Matters From Regulation.

Just last Term, the Court confirmed that the *de minimis* doctrine "is part of the established background of legal principles against which all enactments are adopted, and which all enactments (absent contrary indication) are deemed to accept." *Wisconsin Dep't of Revenue* v. *William Wrigley, Jr., Co.*, 112 S. Ct. 2447, 2458 (1992). Thus, it has been well established that regulatory agencies have inherent authority to decide not to regulate *de minimis* matters, even where the underlying statute is "without exception or qualification." *Permian Basin Area Rate Cases*, 390 U.S. 747, 787 (1968). In short, federal regulatory statutes are "intended to require the elimination, as far as feasible, of significant risks of harm" rather than "to eliminate completely and with absolute certainty any risk." *Industrial Union Dep't, AFL-CIO* v. *American Petroleum Institute*, 448 U.S. 607, 641 (1980) (pl. op.).

The Court adopted the same principle almost 80 years ago in interpreting the first federal food and drug law, when it held that the prohibition against the addition to food of "any" poisonous or deleterious ingredient that "may render" it "injurious to health" applied only if the substance represented a reasonable possibility of harm to human health: if a food "cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such [food], though having a small addition of poisonous or deleterious ingredients, may not be condemned." *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399, 411 (1914) (interpreting the Food and Drugs Act of 1906).

The *de minimis* principle has retained its vitality under the current FFDCA. When Congress passed the Act in 1938, it preserved the 1906 prohibition, along with the Supreme Court's interpretation of it in *Lexington Mill*. *See* 21 U.S.C. 342(a)(1); *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153,

161 (1958). Other food safety provisions embody the same standard. *See, e.g., United States* v. *1,500 Cases More or Less, Tomato Paste*, 236 F.2d 208, 215 (7th Cir. 1956) (statute's prohibition against "any" filth in food is not violated by quantities "so low that they are * * * insignificant and of no consequence").

The court of appeals departed from this principle by requiring an express statutory source for EPA's *de minimis* authority under the Delaney Clause. As the cases cited above make clear, there is a presumption of *inherent* administrative authority to exclude *de minimis* matters, which can only be overcome by the plainest showing of legislative intent. *See also Alabama Power Co.* v. *Costle*, 636 F.2d 323, 360-61 (D.C. Cir. 1979). No such showing is possible here, because Congress did not expressly deny agencies their inherent *de minimis* powers in the Delaney Clause, and the legislative history shows that Congress similarly did not harbor an intent (unexpressed in the statute) to require agencies to prohibit substances that present *de minimis* risks.

B. The Legislative History Supports The *De Minimis* Policy.

When Congress passed the Food Additives Amendment of 1958, it shifted the burden of proving safety to industry, but it retained the same safety standard adopted in 1906 and 1938, that is, "a reasonable certainty that no harm will result." H.R. Rep. No. 2284, 85th Cong., 2d Sess. 4 (1958); S. Rep. No. 2422, 85th Cong., 2d Sess. 6 (1958). Both the House and Senate emphasized that this standard "does not — and cannot — require proof beyond any possible doubt that no harm will result under any conceivable circumstance." *Id.*

It was in this context that Congress considered whether to add Representative Delaney's proposed anti-cancer clause to the food additive bill. The FDA and its parent, the Department of Health, Education, and Welfare (HEW), initially opposed the

clause on the ground that it was unnecessary in light of the general safety requirement of the bill. *See Food Additives: Hearings Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 85th Cong., 1st & 2d Sess. 38-39 (1957 & 1958). The Administration ultimately dropped its opposition on the assurance that FDA would retain the same scientific discretion under the Delaney Clause that it possessed under the general safety standard. *See* 104 Cong. Rec. 17415 (1958). The Delaney amendment was seen simply as a vehicle "to allay any lingering apprehension * * * of those who desire an explicit statutory mandate on this point." *Id.*

The foregoing quotation is from the same Congressional Record page cited by the court of appeals as its only support for the proposition that HEW interpreted the Delaney Clause as depriving it of all administrative discretion. Pet. App. 9a. We submit that a fair reading of the page shows precisely the opposite. In fact, the Administration there suggested anti-cancer language that would give FDA the desired discretion, language that ultimately was adopted by Congress in virtually identical form.

The Senate Report confirmed the Administration's view that the Delaney Clause did not establish a higher hurdle than the general safety standard itself. The Report expressly stated the Committee's belief that "*the bill reads and means the same with or without the inclusion of the [Delaney] clause.*" S. Rep. No. 2422, *supra*, at 11 (emphasis added). The Report continued, "This is also the view of the Food and Drug Administration." *Id.* Thus, while the clause "focus[ed] our attention on the cancer-producing potentialities of various substances" (*id.* at 10), it did not substantively change the law in any respect.

Because of its last-minute inclusion in the food additive legislation, the Delaney Clause was a major focus of concern in the food industry. FDA Commissioner Larrick personally met

with many industry representatives to emphasize that the Delaney Clause was not rigid or inflexible. He assured them that the legislative history was clear that the clause was to be interpreted and applied identically to the general safety provisions. Based on this assurance, the industry withdrew its opposition to the bill. *See* Brady, *Responsibility, Freedom and the Law*, 17 Food Drug Cosm. L.J. 323, 326 (1962).

The Administration's interpretation of the law after enactment supports the *de minimis* interpretation. A scientific panel convened by the President's scientific advisor reaffirmed that the Delaney Clause must be applied using a "'rule of reason' based on scientific judgment." 106 Cong. Rec. 15380-81 (1960). The report accurately predicted that developments in scientific methodology eventually would allow agencies to estimate "the probability of cancer induction from a particular carcinogen * * * by weighing scientific evidence as it becomes available." *Id.* The report concluded, "an area of administrative discretion based on the rule of reason is unavoidable if the clause is to be workable." *Id.*

C. The Court of Appeals Ignored the *Chevron* Doctrine That Courts Should Defer To Reasonable Agency Interpretations of Inconsistent or Ambiguous Statutory Provisions.

In *Chevron*, 467 U.S. 837, this Court held that courts must defer to a reasonable administrative statutory interpretation rather than substitute their judgment for that of the experts charged by Congress with applying the law. This is the touchstone of judicial review of agency action. The court below ignored this principle, failing even to cite *Chevron*.

The court of appeals apparently thought deference inappropriate because, in its view, EPA departed from unambiguous statutory language. As already discussed, that view ignores the inherent authority both EPA and FDA possess

to exclude *de minimis* risks from regulation. That authority makes the *de minimis* policy a reasonable one, deserving of deference, with respect to any food additive subject to section 409.

The arguments in favor of EPA's decision in this case are all the more compelling because of the complex and conflicting statutory provisions applicable to pesticides. In critical respects, the statutory scheme governing pesticides is ambiguous and uncertain. EPA's policy at issue here represents precisely the sort of pragmatic administrative reconciliation of unclear statutory directives to which the courts are required to pay deference. The court below failed to appreciate how EPA's decision faithfully implements a reasonable interpretation both of the statutory language and of the congressional design. Had the court done so, it would have been required to uphold that decision under *Chevron*.

The "precise question" (467 U.S. at 842-43) in this case is whether residues of an approved pesticide that concentrate in processed food must be forbidden entirely if the pesticide includes cancer in experimental animals even though the residues may be approved in the raw commodity and even though they would be lawful in the processed food if they did not concentrate. More generally, the issue is how Congress wished the risk of carcinogenicity to be addressed under the three statutory provisions that govern the use of pesticides in food production -- FIFRA, section 408 of the FFDCA (the Miller Pesticide Amendment of 1954), and section 409 of the FFDCA (the Food Additives Amendment), which alone includes the Delaney Clause. A balanced, thorough analysis of these laws, including the history of the Food Additives Amendment, demonstrates that Congress did not specifically address this question.

In denying the petition for revocation of four pesticides on the grounds that they pose only a *de minimis* risk, EPA

recounted at some length the inconsistent standards and overlapping coverage of sections 408 and 409 of the FFDCA, and of the FIFRA. Pet. App. 13a - 25a. *See* National Research Council, *Regulating Pesticides in Food: The Delaney Paradox* (1987). Briefly stated, EPA must consider the degree of risk posed by a pesticide and the benefits it provides in establishing a tolerance under section 408 for residues of the pesticide on a raw commodity. A number of carcinogenic pesticides have been approved under section 408 on the ground that they present only a negligible risk of cancer. Under the flow-through provision of section 402(a)(2)(C), residues of approved pesticides — including carcinogens — that remain in the commodity after processing are permitted if they do not exceed the section 408 tolerance. Residues that concentrate in the processed food above the raw product tolerance level are deemed by EPA to render the food adulterated unless they are sanctioned by a supplemental section 409 food additive regulation. But if the pesticide presents even a trivial risk of cancer, the Delaney Clause in section 409 — which has no counterpart in section 408 — may be read as precluding issuance of a food additive regulation. As a result, "the same pesticide residues which may be legal on a raw food could render a processed food adulterated" if the pesticide concentrates during processing. *Id.* at 20a.

In order to avoid this "Delaney paradox" in the regulation of pesticides that involve only a negligible risk of cancer, EPA concluded that it could reconcile the apparently conflicting messages of the statute by interpreting the Delaney clause in section 409 as not precluding approval of residues that posed only a *de minimis* risk of cancer. The agency reasoned:

> [t]here is sufficient flexibility in the statutory framework to apply a standard to the evaluation of pesticides under section 409 which both

> ameliorates the most extreme effects of the Delaney paradox and protects the public health.

Id. at 15a. The court of appeals refused to accept EPA's adoption of a *de minimis* gloss on the Delaney Clause as a means of reconciling the inconsistent safety standards of sections 408 and 409 as they apply to pesticide residues in raw and processed foods. In reaching this conclusion, the court claimed:

> The statute unambiguously provides that pesticides which concentrate in processed food are to be treated as food additives, and these are governed by the Delaney food additive provision contained in section 409. If pesticides which concentrate in processed foods induce cancer in humans or animals, they render the food adulterated and must be prohibited.

Id. at 8a.

Contrary to the court of appeals' assertion, there could be no stronger case for application of *Chevron*'s wise guidance to reviewing courts. Yet the court of appeals did not simply fail to follow this Court's guidance; it wholly ignored *Chevron*, dismissed EPA's painstaking effort to reconcile the divergent directives of the laws it is responsible for administering, and substituted its own, self-described "plain meaning" interpretation of a set of statutory provisions whose precise meaning in this context is ambiguous at best.

The court's conclusory assertion that the Act is clear and unambiguous in its application to pesticide residues in processed foods is squarely contradicted by the language of the Act itself. The definition of a "food additive" in section 201(s) of the FFDCA includes exceptions not only for a pesticide residue "in or on" a raw agricultural commodity, and for a pesticide "intended for use" on such commodities, but also for a pesticide "to the extent that it * * * is used" on a raw commodity. On

its face this latter exception precludes regulation of a pesticide as a food additive to the extent that it "is used" on an agricultural commodity, whether or not the commodity is subsequently processed or otherwise altered.[2]

The exception in section 201(s)(2) for a pesticide that "is used" on an agricultural commodity was added late in the 1958 legislative process by the House Committee as one of several "clarifying changes" in the bill, but without further explanation. 104 Cong. Rec. 17414 (Aug. 13, 1958); *compare* H.R. 13254, 85th Cong., 2d Sess. (July 1, 1958), p. 2, lines 17-18; *with* H.R. 13254, 85th Cong., 2d Sess., as reported (July 28, 1958), p. 19, line 2. Neither the Committee Report nor the floor debate referred to the inconsistency between the section 201(s)(2) exclusion of a pesticide from food additive regulation once it is used on a crop, and the flow-through provision in section 402(a)(2)(C) providing that a pesticide residue in a processed food will not be deemed unsafe under section 409 (and its Delaney Clause) if the concentration of the pesticide is not greater than the section 408 tolerance for the pesticide on the raw commodity. If section 201(s)(2) means what it says, there appears to be no point to the flow-through language of section 402(a)(2)(C). In administering the pesticide provisions of the Act, both FDA prior to 1970, and EPA thereafter, have chosen to overlook the section 201(s)(2) food additive exception for a pesticide that is used on a crop, and instead have promulgated food additive regulations under section 409 for approved pesticides that may concentrate in processed foods.

This approach of issuing a food additive regulation for a

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[2] In *United States* v. *Ewig Bros. Co.*, 502 F.2d 715 (7th Cir. 1974), the court held that DDT residues in processed fish resulting from environmental contamination, rather than from the lawful use of the pesticide in the production of the raw fish, were subject to regulation as food additives. The court was thus not faced with application of the exception in section 201(s)(2) for a pesticide "to the extent that it is * * * used in the production * * * of any raw agricultural commodity."

pesticide that concentrates in processed food not only sidestepped the statutory interpretation issue posed by section 201(s)(2). It also made it unnecessary for the agency to interpret and apply the requirement in the flow-through provision of section 402(a)(2)(C) that the residue in the processed food "*when ready to eat*" must not exceed the raw product tolerance. Rather than attempting to evaluate pesticide residues in concentrated processed foods at the enforcement stage by applying the imprecise "when ready to eat" standard, EPA has chosen to avoid uncertainty in compliance and enforcement by issuing easily applied section 409 regulations.

EPA's decision to issue food additive regulations for pesticides that may concentrate in processed foods appeared to make good regulatory sense. Strict application of the section 201(s)(2) exception would leave such residues subject to regulation only under the general safety standard of section 402(a), rather than under the licensing provisions of section 409. Furthermore, the issuance of food additive regulations based on an assumed concentration factor had the added benefit of avoiding the difficulty in applying the "when ready to eat" enforcement standard in section 402(a)(2)(C). It does not appear that EPA ever publicly addressed the significance of "or is used" in section 201(s)(2) or "when ready to eat" in section 402(a)(2)(C), or that those affected by pesticide regulation publicly objected to EPA's practice of issuing section 409 regulations for pesticides that concentrated in processed foods. This *sub silentio* approach to these issues is understandable, for EPA would have no reason to raise questions concerning its own implementation of the Act, and the affected industries (pesticide makers, farmers, and processors) were apparently content with the practical effectiveness of the EPA approach.

Problems with the EPA practice of requiring section 409 regulations for pesticides that concentrate in processed foods began to arise, however, when a number of approved pesticides

were found to be animal carcinogens. The benefit/risk standard of section 408 authorized EPA to ignore negligible risks, including a risk of cancer, but the Delaney Clause in section 409 clearly threatened the legal status of pesticides in some processed foods. This puzzling interplay among sections 408, 409, and 402(a)(2)(C) gave rise to the paradoxical result that a carcinogenic pesticide would be allowed in processed foods that do not concentrate, but forbidden in those that do. After extensive review of the issue by the EPA and by the special NAS Committee in *The Delaney Paradox*, the agency concluded that interpretation of the Delaney Clause to incorporate a *de minimis* risk exception would advance the diverse goals of pesticide regulation under section 408, food additives regulation under section 409, and Congress' attempt to reconcile them in section 402(a)(2)(C). Pet. App. 12a.

It can thus be seen that the EPA *de minimis* policy serves as a means of reconciling inconsistent, overlapping and ambiguous statutory language concerning the status of pesticide residues in processed foods. Under these circumstances, the court of appeals decision is squarely at odds with *Chevron*'s demand for deference and with this Court's application of that requirement to interpretation of the adulteration provisions of the FFDCA. *See Young* v. *Community Nutrition Institute*, 476 U.S. 974, 980-81 (1986) (reversing a court of appeals decision that failed to defer to the FDA's interpretation of ambiguous language in section 406 of the FFDCA).

III. THE *DE MINIMIS* POLICY IS CONSISTENT WITH ADMINISTRATIVE PRACTICE.

The court of appeals based its decision in part on its belief that the Delaney Clause has been interpreted as "an absolute bar to all carcinogenic food additives." Pet. App. at 9a. This understanding of administrative practice is erroneous. In fact, the *de minimis* policy is consistent with FDA's and EPA's historical and present implementation of the Delaney Clause.

Through the *de minimis* interpretation and other policies under the Delaney Clause, the agencies have sought to protect the public from real risks while avoiding the needless prohibition of substances that are associated with at most a trivial risk of cancer.

Prior to 1958, FDA interpreted the general safety clauses of the FD&C Act to bar the use of animal carcinogens because the state of toxicology did not then permit the assessment of human risks. *See*, *e.g.*, 15 Fed. Reg. 321 (January 19, 1950); 19 Fed. Reg. 1239 (March 5, 1954). FDA continued the same policy after enactment of the Delaney Clause. In the only two cases in which it applied that provision before 1973, it banned two carcinogenic additives without attempting to determine what magnitude of risk they presented, since the analytical tools to do so were not yet sufficiently developed. *See* 32 Fed. Reg. 5675 (April 7, 1967); 34 Fed. Reg. 19073 (December 2, 1968).

Beginning in 1973, FDA has consistently used the newly available techniques of quantitative risk assessment to approve or permit the continued use of substances that present only a *de minimis* risk of cancer. *See* P. Hutt & R. Merrill, *Food and Drug Law*, chapter 8 (2d ed. 1991). These agency decisions follow logically from the 1958 contemporaneous administrative interpretation of the Delaney Clause as embodying the same scientific discretion that is inherent in the other safety provisions of the Act. *See* page 10, *supra*. As science has continued to develop, FDA has used the tools at its command to protect the public health from genuine risks, while at the same time recognizing that the public health is not served by needlessly banning substances that do not present any cognizable risk of human cancer.

For example, under FDA's "constituents policy," a carcinogenic impurity or other constituent of a food additive or color additive is not subject to the Delaney Clause, and thus the additive as a whole can be approved under the general safety

provisions, if use of the additive presents only an insignificant carcinogenic risk. The Sixth Circuit upheld this policy in *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984) (per curiam). Similarly, carcinogenic substances that migrate from food contact materials into food may be excluded from the definition of "food additive" if their use presents only a *de minimis* risk of cancer. *See Monsanto Co.* v. *Kennedy*, 613 F.2d 947 (D.C. Cir. 1979). By the same logic, substances that present a *de minimis* cancer risk can be regarded as generally recognized as safe (GRAS) and therefore similarly excluded from the food additive definition. *See Public Citizen* v. *Young*, 831 F.2d 1108, 1119-20 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988). While policies such as these are not in dispute in this case, they demonstrate the reasonableness of the *de minimis* policy and its consistency with other FDA public health initiatives.

EPA also has applied the "constituents policy" in granting food additive approval for the pesticide dicamba in sugarcane molasses. 48 Fed. Reg. 50528 (November 2, 1983). EPA concluded that the nitrosamine contaminant in dicamba, although an animal carcinogen, posed only a *de minimis* human cancer risk. Thus, contrary to the Ninth Circuit's holding, both FDA and EPA historically have applied *de minimis* principles in interpreting section 409 and the Delaney Clause.

IV. THE SOLICITOR GENERAL'S OPPOSITION TO REVIEW IN THIS CASE IS INCONSISTENT WITH HIS POSITION IN AN EARLIER COLOR ADDITIVE CASE.

The government's opposition to the petition in this case is inconsistent with the Solicitor General's position before this Court in a case involving the color additive Delaney Clause, *Cosmetic, Toiletry and Fragrance Ass'n* v. *Public Citizen*, No. 87-1194. There, the government opposed a certiorari petition filed by the industry intervenor principally on the grounds that the Court should wait for a food additive case (which would be

more important as a practical matter and would more directly implicate the critical 1958 legislative history) and that the views of the relevant agencies, including EPA, had not yet been finalized. *See* Gov't Br. in Opp., No. 87-1194, at 7-9. The present case arises directly under the 1958 food additive Delaney Clause, and the government's administrative interpretation of that provision has now been established, as shown by EPA's lengthy Federal Register notice announcing, explaining, and applying the *de minimis* policy. The government's opposition to the present petition thus represents a 180-degree shift from its earlier position before this Court. While the government notes that EPA is currently considering a change in its pesticide tolerance policy (Br. in Opp. 8-9), that fact alone provides no basis for denying the petition here. The possibility that EPA might at some unknown time in the future change its tolerance policy as a response to the decision below does not refute the substantial adverse impact of that decision, which represents a final judicial determination that the *de minimis* policy is invalid.

CONCLUSION

The petition for a writ of certiorari should be granted.

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Supreme Court, U.S.
FILED
FEB 18 1993
OFFICE OF THE CLERK

No. 92-800

IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Petitioner,
v.
KATHLEEN E. LES, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

SUPPLEMENT TO BRIEF OF THE PRIVATE PARTY RESPONDENTS IN OPPOSITION

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SUPPLEMENT TO BRIEF OF THE PRIVATE PARTY RESPONDENTS IN OPPOSITION

The private party respondents submit this supplemental brief pursuant to Rule 15.7.

Petitioner has filed a supplemental brief setting forth a portion of a press release issued by EPA in conjunction with certain lists of pesticides, but has failed to provide the Court with the full text of that document. In particular, petitioner has ignored portions of the press release stating that the lists of pesticides are tentative and that EPA has not determined whether or not tolerances for these pesticides will need to be revoked. EPA's press release states:

> For several reasons, the pesticide uses eventually affected by the Court's ruling may be considerably smaller than the attached lists. First, EPA has not made a final determination whether these pesticides meet the "induce cancer" standard in the Delaney clause. Second, many of the pesticides uses on the attached lists involve animal feeds, and EPA has not evaluated whether those uses qualify for the limited exemption to the Delaney clause for animal feeds. Finally, the Notice EPA issued on Jan. 19 requesting comment discusses several policy issues, the resolution of which will affect precisely what pesticide uses are affected and the extent of that affect.

EPA Note to Correspondents (Feb. 2, 1993).

Moreover, the listing of the specific pesticides begins with the following paragraph:

> The following lists of pesticides and their uses *may* potentially be affected should EPA be held to a strict interpretation of the Delaney clause. The lists *do not constitute a list of pesticides which EPA has determined to "induce cancer" within the meaning of the Delaney clause*, but rather presents lists of pesticides which *may possibly fall within that standard* based on EPA's evaluation of the potential carcinogenicity of the pesticides under its cancer classification guidelines. Likewise, these lists *should not be viewed as definitive or final* because they include some pesticides that ultimately may not be affected; there also may be additional pesticides that are affected, but are not included in today's list. Because the Agency continues to receive data on carcinogenicity and processing studies through its reregistration program, the number of pesticides and uses could grow considerably. The release of these lists does not affect the regulatory status of any of the pesticides or uses listed. If EPA proposes to revoke tolerances under the Federal Food, Drug and Cosmetic Act, the Agency will use appropriate procedures in each instance, including seeking notice and comment where appropriate.

Pesticide Uses Potentially Affected By Revocation of All Section 409 and Corresponding Section 408 Tolerances (Feb. 2, 1993) (emphasis added). The full text of both documents, as well as EPA's Statement on Pesticide Regulation, is provided in the appendix to this brief.

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APPENDIX

APPENDIX

United States Environmental Protection Agency

Communications, Education, And Public Affairs (A-107)

EPA ENVIRONMENTAL NEWS

STATEMENT ON PESTICIDE REGULATION

2/2/93

EPA Administrator Carol M. Browner today is releasing a list of some 35 chemicals for comment on possible cancellation. The action comes in response to a court decision regarding the Delaney Clause. Contrary to the impression left by published reports, Administrator Browner has at no time said that she wants to relax the Delaney Clause. It is the Administration's position that food safety laws need to be improved in order to give the public more protection, not less. As she moves forward with the list of chemicals for comment on possible cancellation, she does plan to confer carefully with Congressional leadership and other interested parties including environmental and agricultural groups on what course might be best for assuring safer pesticide laws. Minimal risk standards that would make Delaney consistent with other pesticide and environmental laws have been recommended by the National Academy of Science, however Administrator Browner reaffirmed her position that all options for improving food safety remain under review. She stresses EPA's commitment to the safety of the food supply in this country, and looks forward to developing a cooperative dialogue to resolve this important issue.

United States
Environmental Protection
Agency

Communications, Education,
And Public Affairs
(A-107)

EPA NOTE TO CORRESPONDENTS

TUESDAY, FEBRUARY 2, 1993

The U.S. Environmental Protection Agency has compiled the attached lists of pesticides and their uses to evaluate which pesticide uses may possibly be affected by the recent Ninth Circuit Court of Appeals decision (*Les vs Reilly*) concerning the Delaney clause. These lists are being released in conjunction with a notice issued on Jan. 19 soliciting public comment on a variety of issues concerning the Delaney clause and the court decision, namely whether EPA should modify its policy for regulating pesticides in processed food (Jan. 19 press release attached). Whether or not many of these uses are affected depends on the resolution of several complex scientific and policy issues described in that notice. Nonetheless, these lists will provide those people making comments with a better understanding of the potential impact of the Court's decision.

"EPA does not believe that the pesticides in the following lists pose an unreasonable risk to public health, based on available data," said EPA Administrator Carol Browner. "Thus, the current debate is not about health risks, but about the legal interpretation of the statute. However, the Agency does believe that the impact of the Ninth Circuit Court's decision upon pesticide users and food processors could be substantial. We will be working closely with members of Congress, appropriate federal agencies and other interested parties to assure that appropriate action is taken to address the implementation of the Court decision."

The Delaney clause in the Federal Food, Drug, and Cosmetic Act (FFDCA) provides that no additive (including pesticides) may be approved in processed food if it has been found to induce cancer in man or animals. EPA regulates pesticide residues in food under FFDCA and has interpreted the Delaney clause as subject to an exception for carcinogenic pesticides that pose only a negligible risk. This interpretation was adopted in 1988 upon the recommendation of the National Academy of Sciences.

In July 1992, the Ninth Circuit overturned EPA's interpretation of the Delaney clause, holding that the Delaney clause bars tolerances (maximum allowable levels of residues in food) for carcinogenic pesticides in processed food without regard to the degree of risk. The decision is not yet final, however, because a pesticide industry group has asked the Supreme Court to review the case and a decision as to whether it will hear the case is expected in March.

For several reasons, the pesticide uses eventually affected by the Court's ruling may be considerably smaller than the attached lists. First, EPA has not made a final determination whether these pesticides meet the "induce cancer" standard in the Delaney clause. Second, many of the pesticide uses on the attached lists involve animal feeds, and EPA has not evaluated whether those uses qualify for the limited exemption to the Delaney clause for animal feeds. Finally, the Notice EPA issued on Jan. 19 requesting comment discusses several policy issues, the resolution of which will affect precisely what pesticide uses are affected and the extent of that affect.

Conversely, these lists should not be viewed as definitive or final because there may be additional pesticides that are affected, but are not included in these lists. Because the Agency continues to receive data on carcinogenicity and processing studies through its reregistration and tolerance reassessment programs, the number of pes-

ticides and uses could grow considerably. The release of these lists does not affect the regulatory status of any of the pesticides or uses listed. If EPA proposes to revoke tolerances under the FFDCA, the Agency will use appropriate procedures in each instance, including seeking public notice and comments.

A copy of the Jan. 19 Notice is available to the press by calling Al Heier at 202-260-4374. All others requesting the Notice are asked to call 703-305-5805 or write: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, U.S. EPA, 401 M St. S.W., Washington, D.C. 20460.

John Kasper, Director
Press Services Division

FEBRUARY 2, 1993

PESTICIDE USES POTENTIALLY AFFECTED BY REVOCATION OF ALL SECTION 409 AND CORRESPONDING SECTION 409 TOLERANCES

The following lists of pesticides and their uses may potentially be affected should EPA be held to a strict interpretation of the Delaney clause. The lists do not constitute a list of pesticides which EPA has determined to "induce cancer" within the meaning of the Delaney clause, but rather presents lists of pesticides which may possibly fall within that standard based on EPA's evaluation of the potential carcinogenicity of the pesticides under its cancer classification guidelines. Likewise, these lists should not be viewed as definitive or final because they include some pesticides that ultimately may not be affected; there also may be additional pesticides that are affected, but are not included in today's list. Because the Agency continues to receive data on carcinogenicity and processing studies through its reregistration program, the number of pesticides and uses could grow considerably. The release of these lists does not affect the regulatory statutes of any of the pesticides or uses listed. If EPA proposes to revoke tolerances under the Federal Food, Drug and Cosmetic Act, the Agency will use appropriate procedures in each instance, including seeking notice and comment where appropriate.

List I

The first list contains pesticides that have established section 409 food additive tolerances. Those challenged in court are noted with and asterisk (*).

Registered Pesticide	Raw Crop (408a)	Processed Food/Feed With 409 Tolerance(s)
Acephate	Cotton	Seed Hulls (186.100) Meal (186.100)
	Soybeans	Meal (186.100) Food handling establishments (185.100)

Registered Pesticide	Raw Crop (408a)	Processed Food/Feed With 409 Tolerance(s)
*Benomyl	Apples	Pomace (Dried) (186.350)
	Citrus	Pulp (Dried) (186.350)
	*Grapes	Pomace (Dried) (186.350)
		*Raisins (185.350)
		Raisin Waste (186.350)
	Rice	Hulls (186.350)
	*Tomatoes	*Puree or Catsup (185.350)
Captan	Grapes	Raisins (185.500)
	Corn	Seed (detreated) (186.500)
Dichlorvos		*Packaged goods (Proposed for revocation) (185.1900)
*Dicofol		*Tea (Dried) (Proposed for revocation) (185.410)
Dimethipin	Cotton	Seed Hulls (186.2050)
Dimethoate	Citrus	Pulp (dried) (186.2100)
Ethylene Oxide	Whole Spices	Ground Spices (185.2850)
	Copra, Black Walnut Meats	
*Mancozeb	*Barley	*Bran (185.6300) (revocation proposed)
		Flour (185.6300)
		Milled Fractions (186.6300)
	*Grapes	*Raisins (185.6300
	*Oats	*Bran (185.6300) (revocation proposed)
		Milled fractions (186.6300)
		Flour (185.6300)
	Rye	Flour (185.6300)
		*Bran (185.6300)
		Milled Fractions (186.6300)
	*Wheat	*Bran (185.6300)
		Flour (185.6300)
		Milled Fractions (186.6300)
Methomyl		Dried hops (185.4100)
Norflurazon	Citrus Fruit	Molasses (186.4450)
		Pulp (dried) (186.4450)
		Dried hops (185.4450)

Oxyflurofen	Cotton	Seed Oil (185.4600)
	Peppermint	Oil (185.4600)
	Spearmint	Oil (185.4600)
	Soybean	Oil (185.4600)
*Phosmet	*Cotton	*Seed oil (Crude and Refined) (185.3950)
Propargite	Apples	Dried pomace (186.5000)
	Grapes	Raisins (185.5000), Dried pomace (186.5000)
	Figs	Dried (185.5000)
	Citrus	Pulp (186.5000)
	Hops	Dried hops (185.5000)
	Tea	Dried tea (185.5000)
Simazine	Sugarcane	Molasses, byproducts (185.5350)
		Syrup, byproducts (185.5350)
		Potable water (185.5350)
Thiophanate-methyl	Apples	Pomace (dried) (186.5700)
Triadimefon (Bayleton)	Apples	Pomace (186.800)
	Barley	Milled Fractions, excluding flour (185.800)
	Grapes	Pomace (186.800)
		Raisin Waste (186.800)
	Wheat	Milled Fractions, excluding flour (185.800)
*Trifluralin (Treflan)	*Peppermint	*Oil (185.5900)
	*Spearmint	*Oil (185.5900)

List II

The following list of pesticides do not have established section 409 food additive tolerances, but based upon data indicating concentration during processing, would require food additive tolerances under EPA's current policy.

Registered Pesticide	Crop(s) With Section 408 Tolerance(s)	Processed Food(s) With No Section 409 Tolerance(s)
Acephate	soybean	Hulls
Alachlor	peanuts	Meal
	sorghum	Flour, Bran, and Germ
	soybean	Hulls, Meal
	sunflower seed	Meal

Registered Pesticide	Crops(s) With Section 408 Tolerance(s)	Processed Food(s) With No Section 409 Tolerance(s)
Asulum	sugarcane	Bagasse and Molasses
Atrazine	sugarcane	Bagasse, Molasses
Benomyl	rice	Bran
Captan	apples	Dried Pomace
	grapes	Raisin Waste, Juice and Dried Pomace
	plums	Prunes
	tomatoes	Dried Pomace
Chlorothalonil	soybeans	Hulls
	potatoes	Wet Peel
Dicamba	barley	Hulls, Bran, Pearl Barley
	millet	Hulls, Meal
	oats	Hulls, Rolled Oats
	wheat	Bran, Shorts, Middlings
Dichlorvos		Food handling establishments
Dicofol	apples	Dried Pomace
	citrus	Oil
	grapes	Dried Pomace, Raisins, Raisin Waste
		Dried Hops
Dimethoate	apples	Juice
	citrus	Oil
Hexazinone	sugarcane	Bagasse and Molasses
Lindane	tomatoes	Dried Pomace
Linuren	potatoes	Dry and Wet Peel, Dehydrated Granules, Chips
Manozeb	apples	Dried Pomace
	grapes	Raisin Waste
	sugar beets	Pulp
	wheat	Middlings
Maneb	apples	Dried Pomace
	sugar beets	Pulp
	grapes	Raisin Waste
Methidathion	citrus	Oil
Metiram	apples	Dried Pomace
	sugar beets	Pulp
Metolachlor	peanuts	Meal

Methomyl	wheat	Bran
Oxyflurofen	apples	Dried Pomace
PCNB	potatoes	Wet and Dried peel
	tomatoes	Dried Pomace
Permethrin	tomatoes	Dried Pomace (restricted to fresh tomatoes)
Phosmet	citrus	Oil
Propargite	citrus	Oil
	plums	Prunes
	grapes	Raisin Waste
Simazine	sugarcane	Bagasse
Triadimefon	pineapple	Bran

FILED
FEB 5 1993
OFFICE OF THE CLERK

No. 92-800

IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Petitioner,

v.

KATHLEEN E. LES; FRANCES LES THOMAS;
MANUEL JESUS PEREZ MORALES; DAVID R. PEREZ;
MANUEL R. PEREZ,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

SUPPLEMENT TO PETITIONER'S REPLY

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SUPPLEMENT TO PETITIONER'S REPLY

Pursuant to Rule 15.7, Petitioner wishes to call the Court's attention to the following statement published by Federal Respondents subsequent to the filing of the Solicitor General's brief in opposition:

> The petitioners challenged EPA's February 25, 1991 Final Order in the U.S. Court of Appeals, Ninth Circuit. On July 8, 1992, in *Les v. Reilly*, 968 F.2d 985 (9th Cir.), the court overturned EPA's interpretation that the Delaney clause contains an exception for pesticide uses that present no more than a *de minimis* cancer risk. The court ruled that food additive regulations are barred for any pesticides that are animal or human carcinogens. Although the court's ruling immediately affects only the pesticides involved in the petition, *under the court's interpretation of the Delaney clause, food additive regulations will have to be revoked or denied for dozens of pesticide uses that either have or need such regulations.*
>
> *EPA disagrees with the Ninth Circuit's decision and continues to believe that a de minimis exception is appropriate both as a legal matter and as a matter of public policy. EPA asked the Department of Justice (DOJ) to petition the Supreme Court for a writ of certiorari on behalf of EPA.* The Solicitor General in DOJ makes decisions concerning whether cases involving Federal agencies will be appealed to the Supreme Court. The Solicitor General ultimately decided against

> petitioning the Supreme Court to review this case. The Solicitor General concluded that this case was not one of the small number of Federal cases, from among many presented each year for possible Supreme Court action, that merited a petition for certiorari.
>
> The National Agricultural Chemicals Association (NACA), which intervened in the case supporting EPA's position, has filed a petition with the Supreme Court for a writ of certiorari asking the Supreme Court to overturn the Circuit Court's decision. For the moment, the effect of the Ninth Circuit's decision has been stayed by the filing of NACA's petition with the Supreme Court. EPA does not know when the Supreme Court will rule on NACA's petition. *If the Supreme Court does not agree to hear NACA's petition, or upholds the Ninth Circuit's decision, EPA will be required to revoke the tolerances that were the subject of the California petition. EPA is prepared to act promptly after any adverse Supreme Court action.*

58 Fed. Reg. 7470, 7472 (1993) (emphasis added).[1]

On February 2, 1993, EPA Administrator Browner released lists identifying 35 major agricultural pesticides which may be affected by the Ninth Circuit's ruling. Ms. Browner stated:

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[1] The *Federal Register* notice was signed by former EPA Administrator William K. Reilly on January 19, 1993. On January 29, 1993, it was approved for publication by EPA's new Administrator, Carol M. Browner.

> *EPA does not believe that the pesticides in [these] lists pose an unreasonable risk to public health*, based on available data. . . . Thus, the current debate is *not about health risks*, but about the *legal interpretation of the statute*. However, the Agency does believe that the *impact of the Ninth Circuit Court's decision upon pesticide users and food processors could be substantial.*

Carol M. Browner, Note to Correspondents (Feb. 2, 1993) (emphasis added).

Respectfully submitted,

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